US005382260A

United States Patent [19]

Dormandy, Jr. et al.

[11] **Patent Number: 5,382,260**

[45] **Date of Patent: Jan. 17, 1995**

[54] **EMBOLIZATION DEVICE AND APPARATUS INCLUDING AN INTRODUCER CARTRIDGE AND METHOD FOR DELIVERING THE SAME**

[75] Inventors: **Ray H. Dormandy, Jr.**, San Bruno; **Marcelyn A. Berlo**, San Francisco, both of Calif.

[73] Assignee: **Interventional Therapeutics Corp.**, Fremont, Calif.

[21] Appl. No.: **969,008**

[22] Filed: **Oct. 30, 1992**

[51] **Int. Cl.**[6] **A61B 17/00**

[52] **U.S. Cl.** **606/151**; 606/108; 606/104

[58] **Field of Search** 606/108, 191, 194, 151, 606/159; 604/96, 104, 60; 623/1, 12

[56] **References Cited**

U.S. PATENT DOCUMENTS

5,167,624	12/1992	Butler et al.	606/191
5,226,911	7/1993	Chee et al.	606/191

FOREIGN PATENT DOCUMENTS

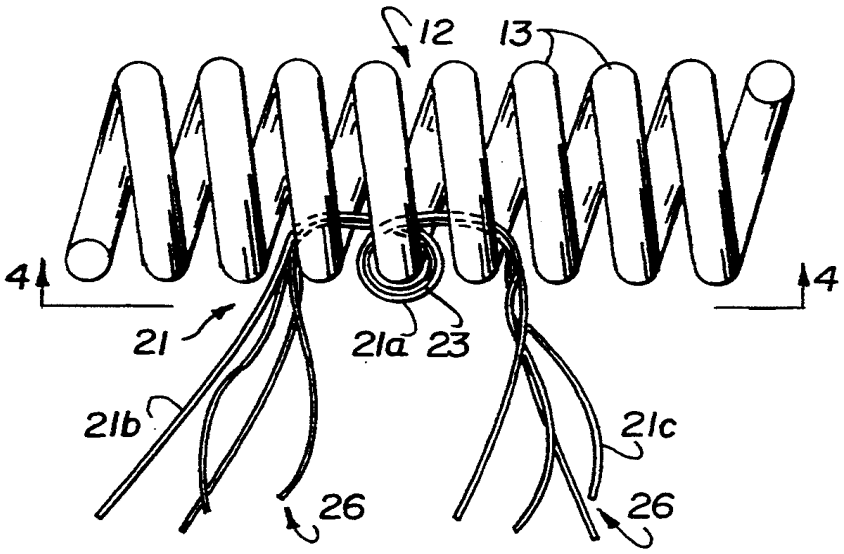
138089	4/1985	European Pat. Off.	606/191
1185845	8/1959	France	604/60

Primary Examiner—Tamara L. Graysay
Attorney, Agent, or Firm—Flehr, Hohbach, Test, Albritton & Herbert

[57] **ABSTRACT**

An embolization device comprising an elongate coil having a plurality of turns formed of a metal which is relatively opaque to x-rays and having rounded ends. A group of fibers is provided. The group of fibers has an intermediate portion and first and second end portions. The intermediate portion is looped about one of the turns to form a loop on one of said turns. The end portions extend interiorly of the coil and outwardly of the coil through two adjacent turns adjacent the turn about which the loop is formed. The ends of the fibers of the end portions of each group are free to move. The group of fibers is free of knots. The loop serves as the sole means for retaining the group of fibers on the coil.

12 Claims, 3 Drawing Sheets



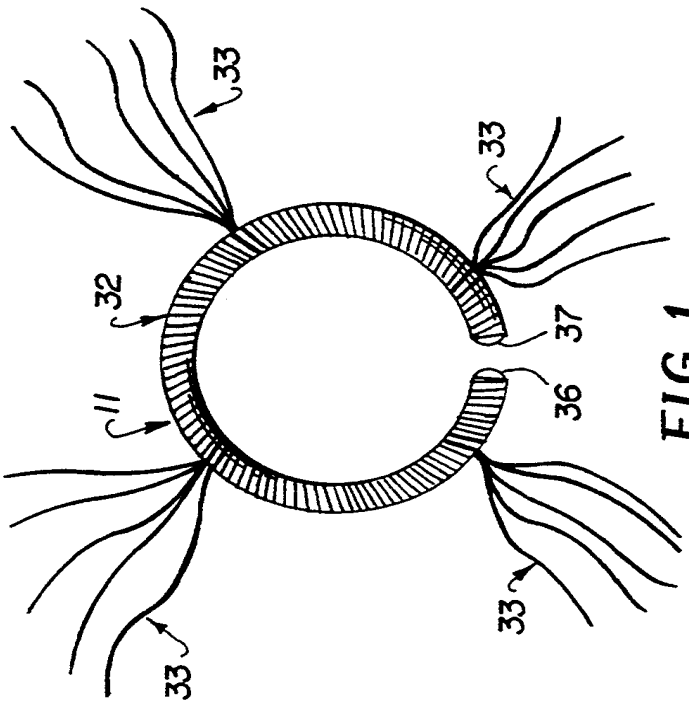


FIG. 1

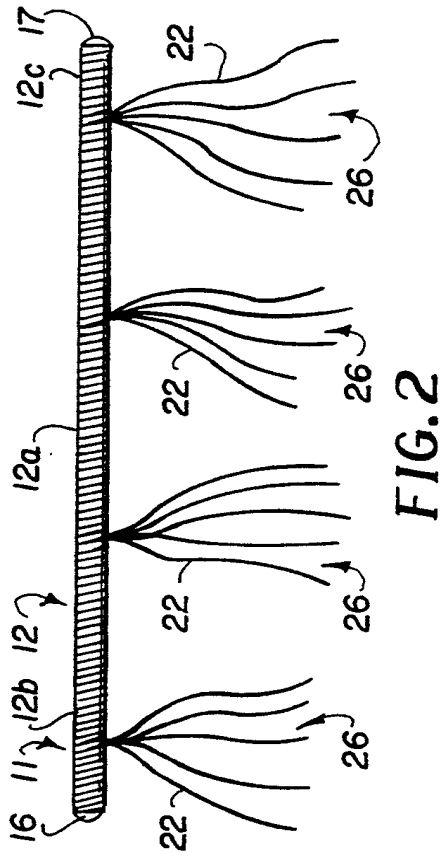


FIG. 2

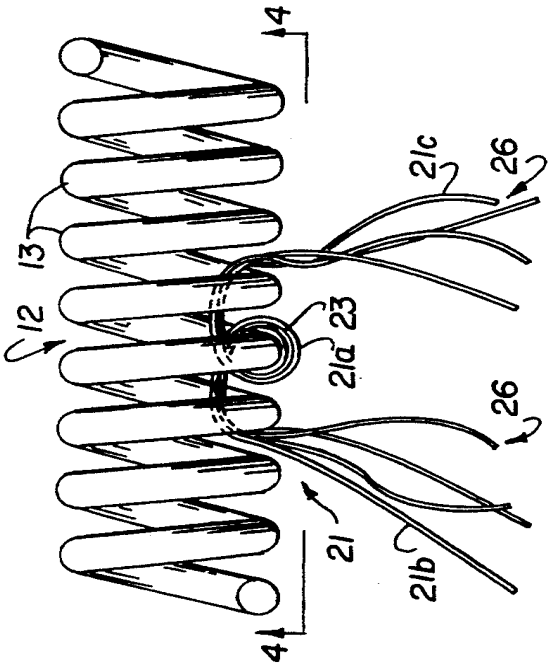


FIG. 3

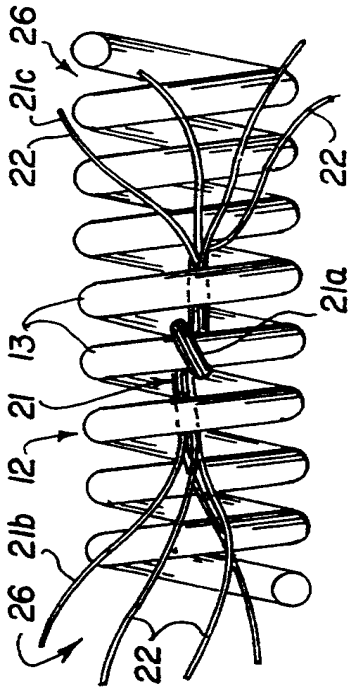


FIG. 4

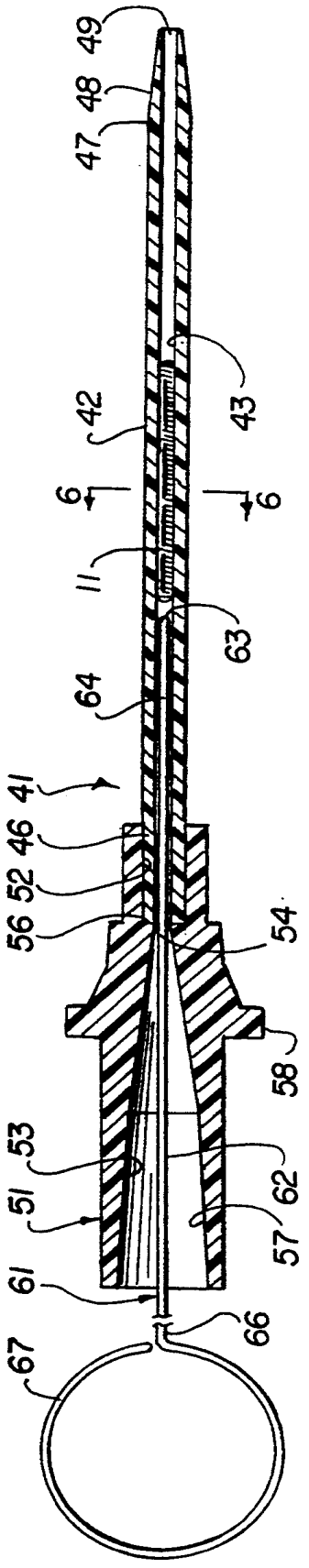


FIG. 5

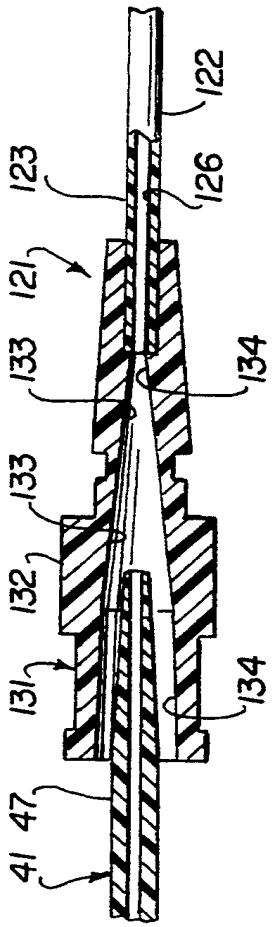


FIG. 10

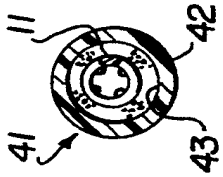


FIG. 6

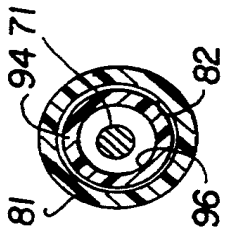


FIG. 8

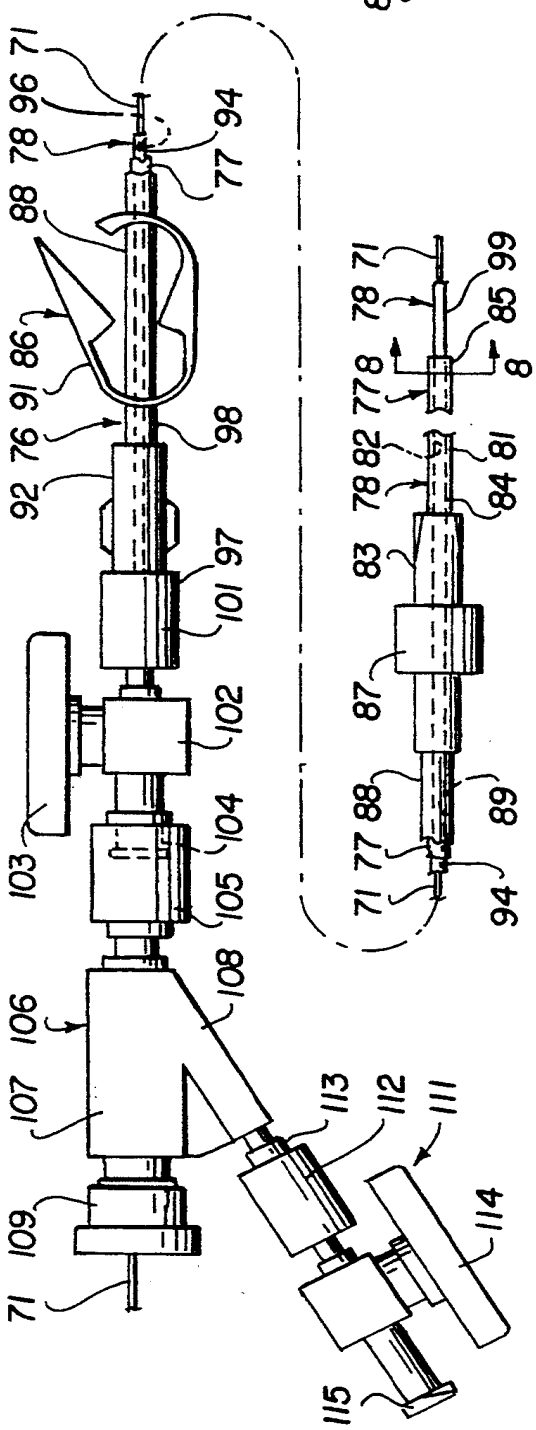


FIG. 7

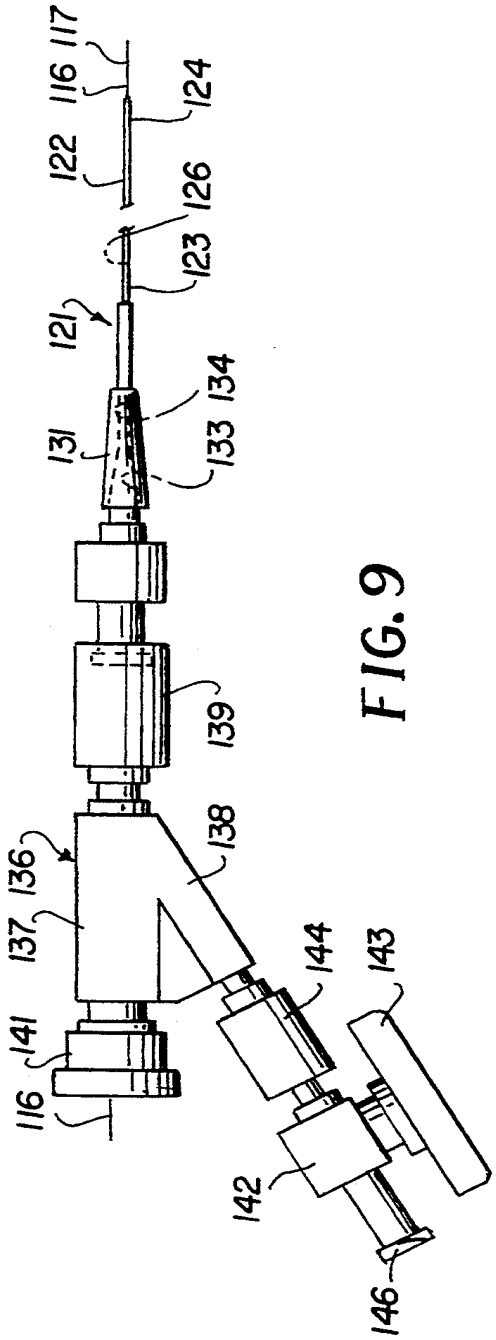


FIG. 9

EMBOLIZATION DEVICE AND APPARATUS INCLUDING AN INTRODUCER CARTRIDGE AND METHOD FOR DELIVERING THE SAME

This invention relates to an embolization device and an apparatus including an introducer cartridge and method for delivering the same in an intravascular procedure.

BACKGROUND OF THE INVENTION

Embolization devices have heretofore been provided which can be used in intravascular procedures. Typically such prior art devices have used coils with fibers attached to the coils. In certain embodiments, the fibers are merely retained by friction between the windings of the coil making it possible for the fibers to become separated from the coil. In other embodiments, the fibers have been tied by knots to the windings of the coil, making the exterior surface of the coil lumpy or bumpy.

Apparatus heretofore provided for delivering such embolization coils to the site have included cartridges for carrying the embolization coils and typically have been in the form of stainless steel tubes serving as shipping containers and also serving as introducers for the coils when they are being introduced into a delivery catheter. It has been found that such stainless steel cartridges do not interface well with the catheter hub making it difficult to introduce the embolization coil from the stainless steel tube and traverse the part of the hub of the catheter before entering the passage of the catheter. There is therefore a need for a new and improved embolization device and a cartridge as a part of an apparatus and method for delivering the embolization device to the desired site in the intravascular system.

SUMMARY AND OBJECTS OF THE INVENTION

In general, it is an object of the invention to provide an embolization device and an apparatus and method for delivering the same to an intravascular site.

Another object of the invention is to provide an embolization device with the fibers carried thereby being securely attached thereto without providing bumpiness to the exterior surface of the embolization device.

Another object of the invention is to provide an introducer cartridge for use in the apparatus and method which has a distal extremity which is tapered to permit it to proximally engage the catheter hub to maintain the alignment of the cartridge with the catheter hub.

Another object of the invention is to provide a cartridge of the above character in which the distal extremity is tapered to facilitate deeper penetration of the introducer cartridge into the catheter hub.

Another object of the invention is to provide a cartridge of the above character in which the friction fit between the introducer cartridge and the catheter hub maintains the alignment of the distal extremity of the cartridge with the internal diameter or passage of the catheter attached to the catheter hub.

Another object of the invention is to provide an introducer cartridge of the above character which is transparent so that movement of the embolization device in the same can be visualized.

Another object of the invention is to provide an introducer cartridge of the above character in which a stylet can be utilized to advance the embolization device out of the introducer cartridge.

Additional objects and features of the invention will appear from the following description in which the preferred embodiments are set forth in detail in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a plan view of an embolization device which has a "C" or circular shape incorporating the present invention.

FIG. **2** is a plan view of another embodiment of an embolization device incorporating the present invention which is in straight.

FIG. **3** being an enlarged partial side elevational view of a portion of an embolization device incorporating the present invention showing the manner in which groups of fibers are secured to the coil.

FIG. **4** is a view looking along the line **4—4** of FIG. **3**.

FIG. **5** is a cross-sectional view of an introducer cartridge with coil and stylet for introducing the embolization device intravascularly.

FIG. **6** is a cross-sectional view looking along the line **6—6** of FIG. **5**.

FIG. **7** is a side elevational view showing a catheter assembly consisting of an introducer catheter and a guiding catheter used as the apparatus for delivering the embolization device to the intravascular site.

FIG. **8** is a cross sectional view taken along the line **8—8** of FIG. **7**.

FIG. **9** is a side elevational view of the delivery catheter used in the apparatus.

FIG. **10** is a partial cross sectional view showing the manner in which the distal extremity of the introducer cartridge is introduced into the hub of the delivery catheter.

In general, the embolization device is comprised of an elongate coil having a plurality of turns and formed of a metal which is relatively opaque to x-rays. At least one group of a plurality of fibers is secured to the coil. The group of fibers has an intermediate portion and first and second end portions. The intermediate portion is looped about one of the turns to form a loop which encircles said one turn and so that the first and second end portions extend interiorly of the coil and then outwardly from the interior of the coil through two adjacent turns on opposite sides of the loop so that the first and second ends are free to permit the fibers in the first and second ends to move about.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

More particularly as shown in FIGS. **1** and **2** in the drawings, the embolization device **11** is comprised of a coil **12**. The coil **12** consists of a plurality of helically wound turns **13**. The coil **12** is formed of a metal which is relatively opaque to x-rays and may be made of a material such as stainless steel, copper, gold, or platinum alloys. Because of their higher radiopacity, a platinum alloy is preferred, as for example a platinum alloy **479** supplied by Sigmond Cohn. The coil **12** can have a primary outside diameter ranging from 0.2 millimeters to 1.3 millimeters and can have a length ranging from 2 millimeters up to 90 millimeters. The wire utilized for forming the coil can have a suitable diameter ranging from 0.002" to 0.006". For a coil having an outside

diameter of 0.4 millimeters, the wire utilized can have a diameter of 0.003".

Typically, the bulk material from which the coil is made is shipped in a primary winding of the desired wire size and outside diameter. The bulk material may then be wound into a secondary coil with secondary outside diameters ranging from 2 millimeters to 10 millimeters. The coil **12** is then cut into appropriate lengths for making coils in accordance with the present invention. Typically, the coils are cut to a length of 1 millimeter longer than the desired length to allow for loss during melting of the ends as hereinafter described. The coil **12** is provided with an intermediate portion **12***a* and first and second end portions **12***b* and **12***c*. The coil **12** can be placed in a fixture (not shown) and then the first end portion **12***b* can be advanced into a torch flame until the end of the coil melts into a smooth, rounded end **16**. The fixture can then be reversed and the other end portion **12***c* advanced into the flame to form a rounded end portion **17** as shown in FIG. **2** of the drawings. After the rounded ends **16** and **17** have been formed, the coil **12** can be ultrasonically cleaned.

Thereafter, the coil can be placed in another fixture, as for example a tube which is then placed in a pin vise for holding the same for fiber attachment. For this purpose, a suitable length of yarn, as for example 10" is cut from a coil of the yarn. The yarn is formed of a suitable synthetic medical grade material such as Dacron. The yarn is comprised of a plurality or groups **21** of filaments or fibers **22** of a suitable size such as 30 Denier. The group **21** of fibers **22**, in other words, the cut-off piece of yarn is then taken and gently pushed between turns **13** in a predetermined location in accordance with the design for the embolization device. For example, only one group of fibers can be utilized or a plurality of groups of fibers can be utilized which are spaced a suitable distance apart, as for example 2 millimeters so that the number of groups of fibers is dependent upon the length of the coil. Each group **21** is pressed into the coil **12** between two adjacent turns **13**. Then, by holding one end of the yarn or group, the other end is brought back through the coil and then successively advanced through two additional turns of the coil. The yarn or group **21** is then brought back and looped over the last turn which has just been passed and then progressively advanced through two additional turns and then brought back to the position shown in FIG. **3**. Thus, it can be seen that the yarn or group of fibers **21** is provided with an intermediate portion **21***a* and first and second ends **21***b* and **21***c*. The group **21** of fibers, after it has been looped about one of the turns of the coil **12** to form a loop **23** that encircles the turn **13** extends from the intermediate portion **21***a* in opposite directions interiorly of the coil for at least one additional turn and then outwardly from the interior of the coil between adjacent turns. In this way, the ends **21***b* and **21***c* of the group **21** are free to form something like tufts **26** extending along one side of the coil **12**. The loop **23** serves as the sole means for retaining the group **21** of fibers **22** on the coil **12**.

As can be seen in FIG. **1**, when the coil **12** is of a suitable length, additional groups of fibers **21** and can be spaced apart longitudinally of the coil and can be secured in the same manner as hereinbefore described and as shown in FIGS. **3** and **4**. Thus, the tufts **26** spaced apart a suitable distance, as for example approximately 2 millimeters along the length of the coil **12**. By way of example, the embolization device **11** can have a coil external diameter of, for example, 2 millimeters and an extended length of 6 millimeters.

In addition to the straight shape for the coil **12** shown in FIG. **2**, a curved coil **32** can be, provided which is circular or C-shaped as shown in FIG. **1**. This C-shaped coil is formed by taking the primary winding **12** and preforming a secondary winding to form the C-shaped coil **32** on a coil-winding apparatus. A tension line is place inside the primary winding **12** and together are wound by a computer-controlled machine onto a mandrel of specified diameter. The secondary winding is then removed from the mandrel and the shape is set in a furnace at a specified time and temperature. The tension line is then removed from the secondary winding. Tufts **33** are provided on the coil **32** and are formed in the same manner as the tufts **26** shown in FIG. **2**. As shown, they are provided on the exterior circumferential surface of the coil and are spaced apart a suitable distance, as for example the 2 millimeters utilized in conjunction with the tufts in FIG. **2**. The coil **32** is provided with rounded ends **36** and **37** formed in the same way as the ends **16** and **17** for the coil **12** in FIG. **2**.

The C-shaped embolization device **32** as shown in FIG. **1** is shown in its at rest or normal position. The embolization device can be in the C-shaped form which is shown in FIG. **1** or, alternatively, it can be in a straight form such as shown in FIG. **2**. However, it is provided loaded into a cartridge **41**. The C-shaped coil **32** can be straightened to the conformation as shown in FIG. **2** and then it can be loaded into the introducer cartridge **41**. The introducer cartridge **41** as shown in FIGS. **5** and **6** consists of an elongate tubular member **42** formed of a clear transparent plastic such as a radiation sterilizable polycarbonate. It is provided with the passage **43** extending therethrough. It can have a suitable size, for example, an inside diameter of 0.023" and an outside diameter of 0.060". Even though the tubular member is bendable, it is still relatively rigid so that it can be utilized as an introducer as hereinafter described. The elongate tubular member **42** is provided with proximal and distal extremities **46** and **47**. The distal extremity is provided with a tapered tip **48**. The introducer cartridge **41** can have a suitable length ranging from 3" to 5", as for example 4.875". The tip **48** can have a suitable length such as 0.3". The tip **48** is tapered with the outside diameter decreasing from the 0.060" for the remaining portion of the tubular member **42** down to approximately 0.030" with the distal extremity of the tip of **48** being rounded at **49**.

A hub **51** is mounted on the proximal extremity **46** of the elongate tubular member **42** and is also formed of the clear radiation sterilizable polycarbonate. The hub **51** is provided with a cylindrical recess **52** which is sized to receive the proximal extremity **46** of the elongate tubular member **42**. The cylindrical recess **52** opens into a tapered conical recess **53** which has a proximal extremity sized so that its interior diameter at **54** of approximately 0.020" is slightly less than or equal to the interior diameter of 0.023" of the passage **43** in the elongate tubular member **42**. The proximal extremity **46** of the elongate tubular member **42** abuts a shoulder **56** provided in the hub **51**. The shoulder **56** extends over or aligns with the proximal extremity of the elongate tubular member **42**. The conical recess **53** can have a suitable length, for example 0.44". The conical recess **53** subtends a suitable angle, as for example approximately 9° from the horizontal and adjoins another conical recess

57 which subtends an angle of approximately 3°. The conical recess 57 can have a suitable length as, for example 0.356". The hub 51 is also provided with a circular flange 58 approximately midway of the conical recess 53 and extending radially or outwardly therefrom. The flange 58 may be provided with a flat (not shown).

As can be seen in FIG. 5, the embolization device 11 is disposed within the passage 43 of the introducer cartridge 41. Because of the small size, the embolization device 11 is typically introduced into the introducer cartridge 41 under a microscope. A tweezer (not shown) is utilized to pick up the embolization device 11 and inserting it into the conical recess 57 and then advancing it into the conical recess 53 and over the shoulder 56 into the passage 43. Thereafter, it can be introduced further into the passage 43 by the use of a stylet 61 (see FIG. 5). The stylet 61 can be of a suitable length such as 8.375" and can be formed of elongate wire 62 of a suitable diameter such as 0.018". It is provided with a rounded tip 63 on its distal extremity 64. The proximal extremity 66 is formed into a circle of the suitable diameter, as for example ¼", which serves as a handle 67 for using the same. By grasping the handle 67, the assembler can introduce the embolization device 11 further into the passage 43 where it will be protected and remain therein until the embolization device is ready to be used as hereinafter described.

The stylet 61 can then be removed and packaged with the introducer cartridge 41 for later use in a sterile package (package not shown).

Let it be assumed that it is desired to use the embolization device 32 and the introducer cartridge 41 in connection with a medical procedure and apparatus to inhibit or stop hemorrhaging occurring in a vessel of the patient, that is, blood is flowing in an undesired manner and it is desired to form a clot of the blood in the vessel. By way of example, the procedure can be utilized in connection with a brain hemorrhage. However, it should be appreciated that the procedure can be utilized in other small vessels in the body to form a clot or embolism in a desired location.

Let it be assumed that a cut has been made in the femoral artery of the patient and a femoral sheath (not shown) of the conventional type has been placed in the femoral artery of the patient. The physician performing the procedure then takes apparatus which includes a conventional guide wire, as for example a 0.038" diameter guide wire 71. The guide wire 71 is provided with a distal extremity which is very flexible. This distal extremity is introduced into the sheath and then advanced through the femoral artery under fluoroscopy through the aortic arch and then through the carotid artery in the neck and then advancing into the desired vessel in the brain to a location or site in which it is desired to place a catheter for forming an embolism in accordance with the present invention.

As soon as the guide wire 71 is in place, a catheter assembly 76 (see FIG. 7) forming a part of the apparatus is utilized which consists of an introducer catheter 77 with a guiding catheter 78 disposed in the same. This catheter assembly 76 is advanced over the guide wire 71 as hereinafter described.

The introducer catheter 77 is comprised of a flexible elongate tubular member 81 with a flow passage 82 therein. The introducer catheter 77 can be of a suitable size, as for example 7.3 French and having a length of 90 centimeters and a flow passage 82 with an inside diameter of 0.070". A female Luer fitting 83 is mounted on the proximal extremity 84 of the flexible elongate tubular member 81. The flexible elongate tubular member 81 is provided with the distal extremity 85. The female Luer fitting 83 is releasably attached to a clamp assembly 86. The clamp assembly 86 consists of a mating Luer fitting 87 of a conventional type and has a relatively short flexible tubular member 88 mounted therein with a suitable outside diameter such as 3/16" and having a flow passage 89 therein of a suitable diameter such as ⅛". The passage 89 is adapted to be clamped to a closed position by a releasable clamp 91 of a conventional type disposed on the tubular member 88. A female Luer fitting 92 is provided on the other end of the tubular member 88 and completes the clamp assembly 86. The clamp 91 is moved to the closed position on the tubular member 88 at such time as all elongate elements have been removed from passage 89, to prevent the flow of blood from the introducer catheter.

The guiding catheter 78 consists a flexible elongate tubular member 94. The guiding catheter 78 can be of a suitable size, as for example 5.0 French and has a length of 110 centimeters and a flow passage 96 with a diameter of 0.044". A male Luer fitting 97 with stopcock is mounted on the proximal extremity 98 of the flexible elongate tubular member 94 which is also provided with a distal extremity 99. As can be seen from the drawings, the flexible tubular member 94 has a length which is great enough so that the distal extremity 99 can extend out of the distal extremity of the introducer catheter 77. The fitting 97 has rotatably mounted thereon a threaded hub 101 which is adapted to mate with the female Luer fitting 92 carried by the clamp assembly extension tubular member 88 so that the guiding catheter 78 can be remained engaged with the clamp assembly 86. A stopcock 102 is formed integral with the fitting 97 and is provided with a handle 103 for moving it between open and closed positions with respect to the passage 96 in the flexible elongate tubular member 94. The stopcock 102 is provided with a female Luer fitting 104 which is adapted to mate with a male Luer fitting 105 carried by a conventional sidearm adapter 106. The sidearm adapter 106 is provided with central arm 107 and a sidearm 108. A hemostatic valve 109 of a conventional type is mounted on the central arm 107 and is adapted to have the guide wire 71 extend therethrough and is adapted to make a seal therewith so that blood cannot flow out of the vessel through the valve 109. A stopcock assembly 111 is mounted on the sidearm 108. It is provided with a male Luer-type fitting 112 which engages the female Luer fitting 113 provided on the side arm 108. It is provided with a handle 114 for moving the valve between opened and closed positions and a female Luer fitting 115.

With the guiding catheter 78 of the type hereinbefore described disposed within the introducer catheter 77 also hereinbefore described and having the distal extremity of the guiding catheter 78 extending beyond the distal extremity 86 of the introducer catheter 77, the distal extremity 99 is positioned over the guide wire 71 and then advanced through the sheath over the guide wire. The entire catheter assembly 76 is advanced at the same time with the guiding catheter 78 within the introducer catheter 77 until the distal extremity of the guiding catheter 78 reaches the desired site determined by the previously positioned guide wire 71.

As soon as the distal extremity 99 is in the proper position, the 0.038" guide wire 71 is withdrawn and a smaller guide wire, typically 0.016" or 0.014" guide

wire **116** having a distal extremity **117** is inserted into a central arm **107** of the sidearm adapter **106** and through the lumen or passage **96** of the flexible elongate tubular member **94** of the guiding catheter **78**. The guide wire **116** is advanced so that it extends slightly beyond the distal extremity **99** of the guiding catheter **78**. At this juncture, the guiding catheter **78** is removed over the guide wire **116** leaving the introducer catheter **77** with clamp assembly **86** in place.

A coil delivery catheter **121** is then utilized and is advanced over the small guide wire **116** until it reaches the desired location or site. The coil delivery catheter **121** as shown in FIG. **9** consists of a flexible elongate tapered tubular member **122** having a proximal extremity **123** and a distal extremity **124**. It is provided with a flow passage **126** having a suitable inside diameter, as for example 0.021" and the tubular member having an outside diameter of 0.028" at distal extremity **124** and an outside diameter of 0.039" at proximal extremity **123**.

A female Luer-type hub **131** is mounted on the proximal extremity **123** of the flexible elongate tubular member **122**. The female Luer-type hub **131** is provided with a conical recess **133** which has a distal extremity **134** with a diameter approximately the diameter of the passage **126**, as for example a diameter of 0.020"–0.023". The conical recess **133** is inclined from the horizontal as viewed in FIG. **10** by a suitable angle, as for example 6.52°, and has a suitable length, as for example approximately 0.585". The conical recess **133** adjoins a conical recess **134** which subtends an angle from the horizontal of approximately 2°. The conical recess **134** has a suitable length, as for example 0.200".

As soon as this delivery catheter **121** has been advanced to the desired location or site over the small guide wire **116**, the small guide wire **116** is removed.

The sidearm **106** can be utilized for the heparin-saline drip to keep the blood flushed out of the introducer catheter **77**.

A sidearm adapter **136** is provided which has a central arm **137** and a sidearm **138**. It is provided with a male Luer fitting **139** which is threaded onto the female hub **131**. A hemostatic valve **141** is provided on the central arm **137** and a stopcock **142** is provided on the sidearm **138** and has a handle **143** for moving the stopcock between opened and closed positions. The stopcock **142** is also provided with a male fitting adapted to mate with the female fitting provided on the sidearm **138**. It also provided with a female-type Luer fitting **146**.

When the delivery catheter **121** is advanced over the wire **116** to the desired location, the valve **109** can be tightened to prevent blood flowing from between the delivery catheter **121** and the sidearm adapter **107**. The valve **141** can also be tightened to prevent the flow of blood between the guide wire **116** and sidearm adapter **136**.

Once the delivery catheter **121** has its distal extremity **124** at the desired location, the valve **141** can be loosened slightly and the guide wire **116** can be removed. Thereafter, the sidearm assembly **136** can be removed. The sidearm may be removed or left attached. The cartridge will pass through the valve when sufficiently opened.

The introducer cartridge **41** is then taken with the embolization device within the same and is pushed into the hub **131** to frictionally lodge it in the same by having its tapered extremity **48** engaging the tapered sidewall **134** of the female hub **131**. By pressing introducer cartridge **41** within the hub, the introducer cartridge is frictionally retained within the hub to hold it in place.

The stylet **61** is then taken and is advanced into the hub **51** and into the passage **43** and engages the embolization device **11** therein and is used to push it out of the introducer cartridge **41** into the passage **126** in the flexible elongate member **122** of the delivery catheter **121**. The advancement of the embolization device **11** can be readily observed because of the transparency of the introducer cartridge **41** and the hub **131**. As soon as the stylet **61** has advanced the embolization device **11** into the passage **126** as far as it can be advanced by the stylet **61**, the stylet **61** is removed. The small guide wire **116** is then taken and its proximal end, which is the stiffer end, is introduced into the hub **131** and into the passage **126** to engage the embolization device **11** and to push the embolization device **11** through the delivery catheter **121** until the embolization device **11** is near the distal extremity **124**. Typically, the embolization device will be from 50 to 75 centimeters from the proximal end of the delivery catheter **121** at this point. Thereafter, the small guide wire **116** is withdrawn and is reversed with its more flexible distal extremity **124** advanced into the hub **131** and into the passage **126** until it again engages the embolization device **11**. The guide wire **116** is then pushed while being viewed under fluoroscopy until the embolization device **11** exits from the tip of the delivery catheter **121**. As soon as the embolization device **11** has exited from the passage **126**, it will then assume its normal C-shape and engage the walls of the vessel in which it is disposed. Its tufts **33** (see FIG. **2**) carried thereby will come into contact with the blood in the vessel.

It should be appreciated that, if desired, additional embolization devices **11** can be placed in the same vessel at the same location in a similar manner by utilizing a introducer cartridge and mounting the same in the hub **131** after the other introducing cartridge has been removed.

After the desired number of embolization devices **11** have been positioned at the desired location, the sidearm **136** can be removed and a contrast agent, as for example a radiopaque dye can be introduced directly into the delivery catheter **121** to visualize directly the blood flow and the degree of embolization which is occurring. When the degree of embolization is satisfactory, the delivery catheter **121** can be removed followed by removal of the introducer catheter **77**. The femoral sheath can then be removed and the opening to the femoral artery can be sutured and, if desired, alternatively it can be temporarily closed by a conventional femoral artery closure (not shown). This makes it possible to perform another embolization procedure if that proves to be necessary to achieve the desired embolism in the vessel of interest.

It is apparent from the foregoing that there has been provided an introducer cartridge and an apparatus which includes an embolization device cartridge and a method for delivering the embolization device to the desired location in a vessel of a patient. The embolization device in the form of a coil has the fibers or filaments attached to the same so that they cannot be accidentally removed from the coil. The coil has a relatively smooth outer surface which does not have lumps or bumps which would be created by tying knots into the fibers to fasten the same to the coil. In addition, there has been provided an introducer cartridge which frictionally engages the hub of the delivery catheter so that it cannot accidentally fall out. The introducer car-

tridge has been formed of a transparent material as has the hub of the delivery catheter so that the movement of the embolization device within and from the cartridge can be readily observed.

What is claimed is:

1. An embolization device comprising an elongate coil having a plurality of turns formed of a metal which is opaque to x-rays and having rounded ends comprising a first group of fibers, said first group of fibers having an intermediate portion and first and second end portions, said intermediate portion being looped about one of said turns to form a loop on one of said turns, the first and second end portions extending interiorly of the coil and outwardly of the coil through two adjacent turns adjacent the turn about which the loop is formed, the ends of the fibers of the first and second end portions of each first group being free to move, said first group of fibers being free of knots and said loop serving as the sole means for retaining the group of fibers on the coil.

2. A device as in claim 1, wherein together with at least one additional group of fibers which are secured to the coil in the manner in which the first group of fibers is secured to the coil and being spaced longitudinally of the coil from the first named group of fibers.

3. A device as in claim 2, wherein said fibers extend outwardly of the coil in the same direction.

4. A device as in claim 1, wherein said coil has a normal C-shaped configuration having a circumference and in which the fibers extend outwardly from the circumference of the coil.

5. A device as in claim 1, wherein said rounded ends are in the form of hemispherical ends.

6. A device as in claim 1, wherein said coil is formed of wire having a diameter of approximately 0.003" wherein said coil has an outside diameter of 0.4 millimeters.

7. A method for introducing an embolization device into a vessel of a patient comprising introducing a first guide wire having proximal and distal extremities into the vessel of the patient so that the distal extremity is disposed in the vicinity of the location in which it is desired to perform an embolization, introducing a catheter assembly comprised of a clamp assembly, an introducer catheter and a guiding catheter having proximal and distal extremities disposed in the introducer catheter over the first guide wire until the distal extremity of the guiding catheter is disposed in the desired location removing the first guide wire, introducing a second guide wire having a proximal end and a distal extremity of a smaller size than the first guide wire into the guiding catheter so that its distal extremity extends beyond the distal extremity of the guiding catheter, removing the guiding catheter from the introducer catheter, advancing a delivery catheter having proximal and distal extremities over the second guide wire until the distal extremity of the delivery catheter is disposed in the vicinity of the desired location, said delivery catheter having a hub formed oil the proximal end thereof which has a conical recess therein, removing the second guide wire, placing an introducer cartridge having a flexible tubular member with proximal and distal extremities with the distal extremity being tapered so that the distal extremity frictionally engages the conical recess in the hub of the delivery catheter, said introducer cartridge having a flow passage extending from the proximal extremity to the distal extremity of the flexible tubular member and having an embolization device disposed in the flow passage, said flow passage having a diameter, the proximal extremity of the flexible tubular member of the introducer cartridge having a hub and having a conical recess therein and having proximal and distal extremities with the distal extremity of the conical recess having a diameter of slightly less than the diameter of the flow passage in the flexible elongate tubular member, introducing a stylet into the hub of the introducer cartridge and advancing the stylet through the flow passage to push the embolization device out of the introducer cartridge and into a passage of the delivery catheter, removing the styler, taking the proximal end of the second guide wire and introducing it through the introducer cartridge and into the passage in the delivery catheter to advance the embolization device to near the distal extremity of the delivery catheter, withdrawing the second guide wire, inserting the distal extremity of the second guide wire into the passage in the delivery catheter and advancing the second guide wire to force the embolization device out of the distal extremity of the delivery catheter to move it into the patient's vessel at the desired location and thereafter removing the second guide wire, the delivery catheter and the introducer cartridge.

8. A method as in claim 7, together with the step of removing the second guide wire, removing the introducer cartridge, inserting a second introducer cartridge having an embolization device into the hub of the delivery catheter so that it is frictionally retained therein, using the stylet to advance the embolization device from the introducer cartridge, utilizing the proximal and distal extremities of the second guide wire to advance the embolization device out of the flow passage in the delivery catheter to place a second embolization device in the desired location, repeating the same sequence and steps until a desired number of embolization devices have been positioned in the desired location in the vessel of the patient.

9. An introducer cartridge and an embolization device for use with a delivery catheter having a proximal end with a hub mounted thereon and having a conical recess therein, said introducer cartridge comprising a flexible elongate tubular member formed of a clear plastic and having a flow passage extending therethrough and having proximal and distal extremities, said flow passage having a diameter, said distal extremity being tapered, and a hub formed of clear plastic secured to the proximal extremity of the flexible elongate tubular member, said hub of the introducer cartridge having a conical recess therein with a proximal extremity and with a distal extremity, the distal extremity of the conical recess having a diameter which is slightly less than the diameter of the flow passage in the flexible elongate tubular member, said embolization device being disposed within the flow passage in the flexible elongate tubular member of the introducer cartridge and being frictionally retained therein.

10. An apparatus for delivery of all embolization device into a vessel in a human body, said apparatus comprising an introducer catheter having proximal and distal extremities and said distal extremity for being disposed in the vessel of the patient in a desired location, a delivery catheter disposed within the introducer catheter and having proximal and distal extremities, the distal extremity of the delivery catheter being disposed beyond the distal extremity of the introducer catheter and being located in the desired location in the vessel of the patient at which it is desired to place at least one

embolization device, said delivery catheter having a hub with a conical recess therein, an introducer cartridge comprising a flexible elongate tubular member formed of a transparent material and having proximal and distal extremities and having a flow passage of predetermined diameter extending therethrough, said distal extremity of the flexible elongate tubular member of the introducer cartridge being tapered and frictionally engaging the conical recess in the hub of the delivery catheter to retain the introducer cartridge ill the hub of the deliver catheter, an embolization device disposed within the low passage of the flexible elongate tubular member of the introducer cartridge and being frictionally retained therein and a hub on the proximal extremity of the flexible elongate tubular member of the introducer cartridge, and having a conical recess therein, said conical recess in the hub of the introducer cartridge having proximal and distal extremities, the distal extremity of the conical recess of the introducer cartridge hub having a diameter slightly less than the predetermined diameter of the flow passage in the flexible elongate tubular member of the introducer cartridge.

11. An apparatus as in claim **10**, together with a stylet, said stylet extending through the hub of the introducer cartridge hub and extending into the flow passage of the elongate tubular member for engaging and pushing the embolization device out of the introducer cartridge, said introducer cartridge hub being formed of a clear plastic material.

12. An introducer cartridge together with a delivery catheter, said introducer cartridge comprising a flexible elongate tubular member formed of a clear plastic and having a flow passage extending therethrough and having proximal and distal extremities, said flow passage having a diameter, said distal extremity being tapered and an introducer cartridge hub formed of clear plastic secured to the proximal extremity of the flexible elongate tubular member, said introducer cartridge hub having a conical recess therein with a proximal extremity and with a distal extremity, the distal extremity of the conical recess having a diameter which is slightly less than the diameter of the flow passage in the flexible elongate tubular member, said delivery catheter having a proximal end and having a delivery catheter hub mounted on the proximal end, said delivery catheter hub having a conical recess therein, said conical recess in the delivery catheter hub being sized so that the tapered distal extremity of the introducer cartridge engages and seats within the conical recess of the delivery catheter hub and is frictionally retained therein.

* * * * *

US005980514A

United States Patent [19]

Kupiecki et al.

[11] **Patent Number: 5,980,514**

[45] **Date of Patent: *Nov. 9, 1999**

[54] **ANEURYSM CLOSURE DEVICE ASSEMBLY**

[75] Inventors: **David Kupiecki**, Cupertino; **Clifford Teoh**, Daly City; **Hong Doan**, Santa Clara; **Son M. Gia**, San Jose; **Erik T. Engelson**, Menlo Park; **Uriel Hiram Chee**, San Carlos; **Mehran Bashiri**, Fremont; **Joseph C. Eder**, Los Altos, all of Calif.

[73] Assignee: **Target Therapeutics, Inc.**, Fremont, Calif.

[*] Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

[21] Appl. No.: **08/690,183**

[22] Filed: **Jul. 26, 1996**

[51] **Int. Cl.**[6] **A61M 31/00**

[52] **U.S. Cl.** **606/32**; 606/108; 606/194; 604/52; 604/104

[58] **Field of Search** 606/32–42, 45–50, 606/108, 191, 194; 604/104, 52; 579/533

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,512,338	4/1985	Balko et al.	606/108
4,739,768	4/1988	Engelson .	
4,878,906	11/1989	Lindemann et al. .	
4,994,069	2/1991	Ritchart et al. .	
5,122,136	6/1992	Guglielmi et al. .	
5,226,911	7/1993	Chee et al. .	
5,250,071	10/1993	Palermo .	
5,261,916	11/1993	Engelson .	
5,354,294	10/1994	Chou .	
5,354,295	10/1994	Gugliemi et al. .	
5,378,239	1/1995	Termin et al.	606/194
5,522,836	6/1996	Palermo	606/108
5,569,245	10/1996	Guglielmi et al.	606/32
5,582,619	12/1996	Ken	606/108
5,607,466	3/1997	Imbert et al.	606/194
5,609,628	3/1997	Keranen .	

FOREIGN PATENT DOCUMENTS

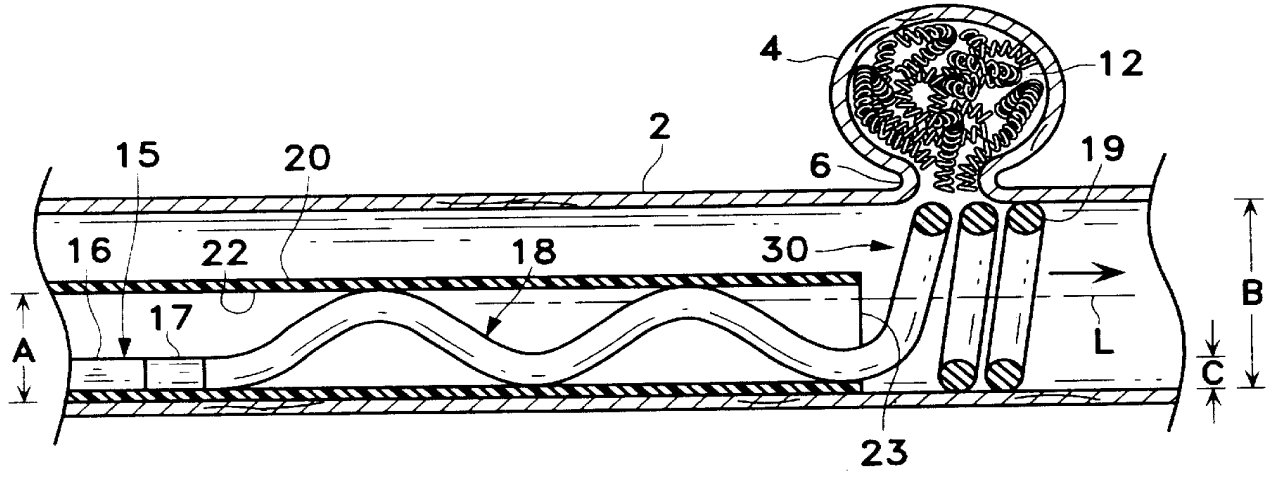
0 547 530A1	12/1992	European Pat. Off. .
0 664 104A2	8/1994	European Pat. Off. .

Primary Examiner—Jennifer Bahr
Assistant Examiner—David M. Ruddy
Attorney, Agent, or Firm—Morrison & Foerster LLP

[57] **ABSTRACT**

This is an artificial occlusion kit for implanting and retaining an artificial occlusion device in a body space adjacent to and extending from a body lumen in a mammal. The includes at least one occlusion device and a retaining device for blocking the migration of the occlusion device out of the occlusion site. The retaining device is radially expandable at a retaining site adjacent the body space to be occluded to a diameter that is sufficient to engage the body lumen wall at the retaining site and form a barrier across the entrance zone of the body space to be occluded. The expanded retaining device also forms a lumen for flow through body lumen at the retaining site. At least one semi-penetrable space may also be provided in the retaining device, allowing introduction of occlusion devices into the body space to be occluded, but preventing subsequent migration of the occlusion devices out of the body space. This semi-penetrable space may also be distensible to allow for delivery of occlusion devices therethrough. An introducer wire or a tapered-tip delivery catheter may be used to distend the distensible space and deliver the occlusion devices. The retaining device structure may further include a radiopaque metal wire wound into a primary helix over an inner core member made of a superelastic alloy of nickel and titanium. An implantable medical device assembly is also provided, having the structure described for the retaining device of the novel artificial occlusion kit, and which is attached to an elongate pusher via a sacrificial link that is electrolytically dissolvable.

21 Claims, 10 Drawing Sheets



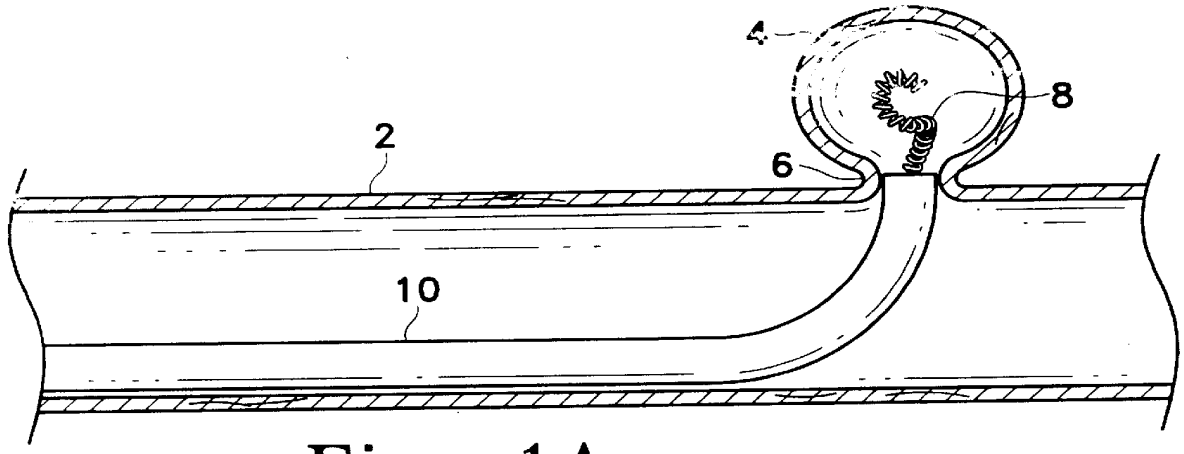


Fig. 1A

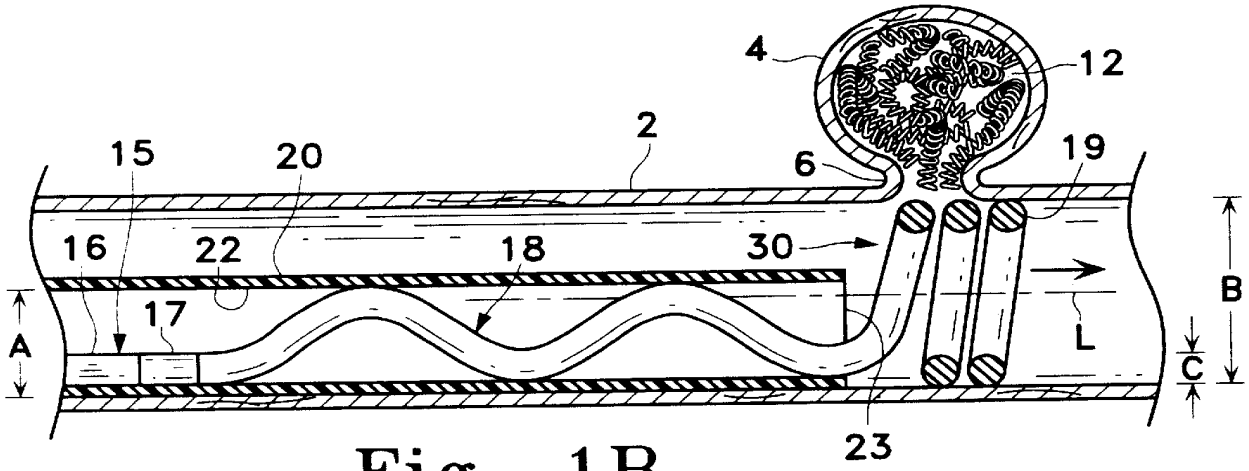


Fig. 1B

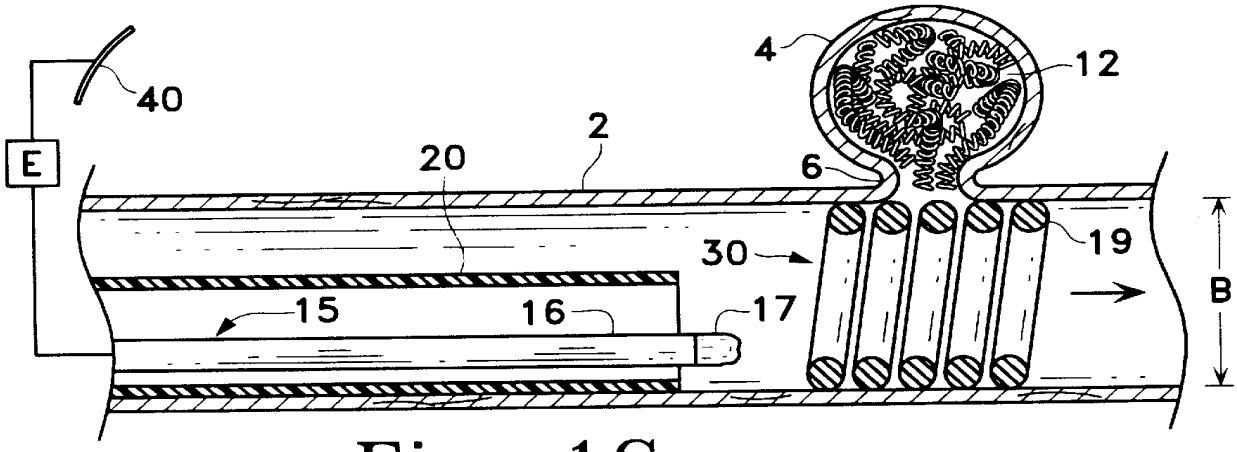


Fig. 1C

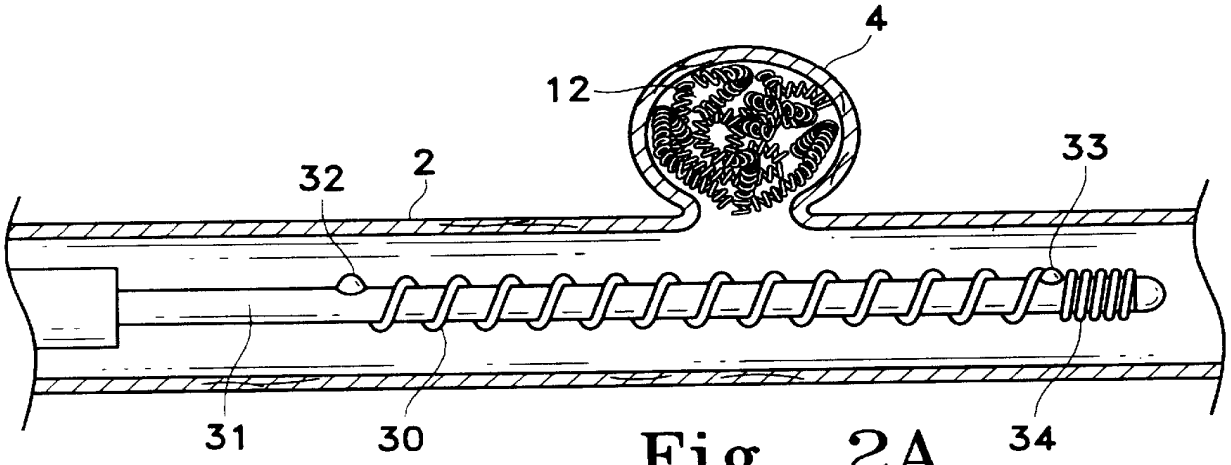


Fig. 2A

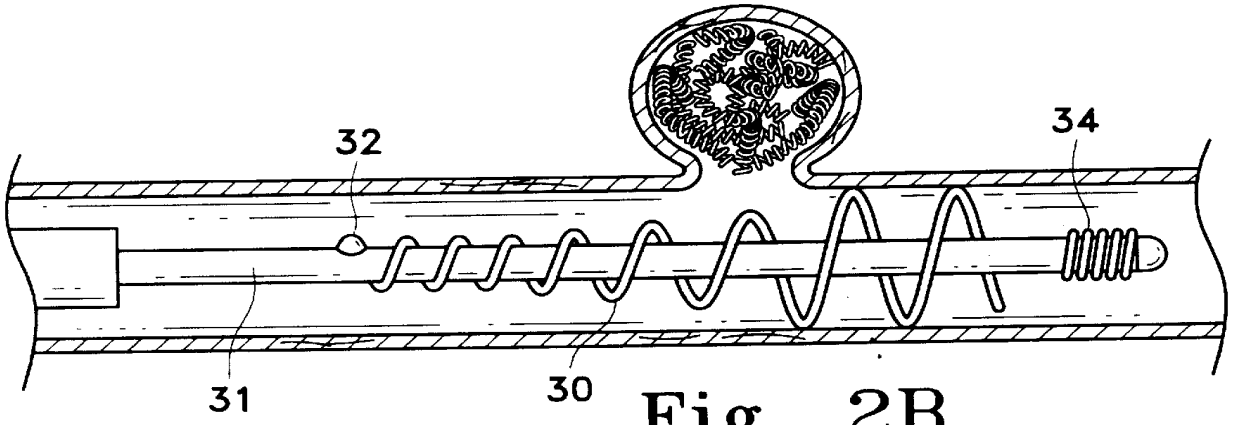


Fig. 2B

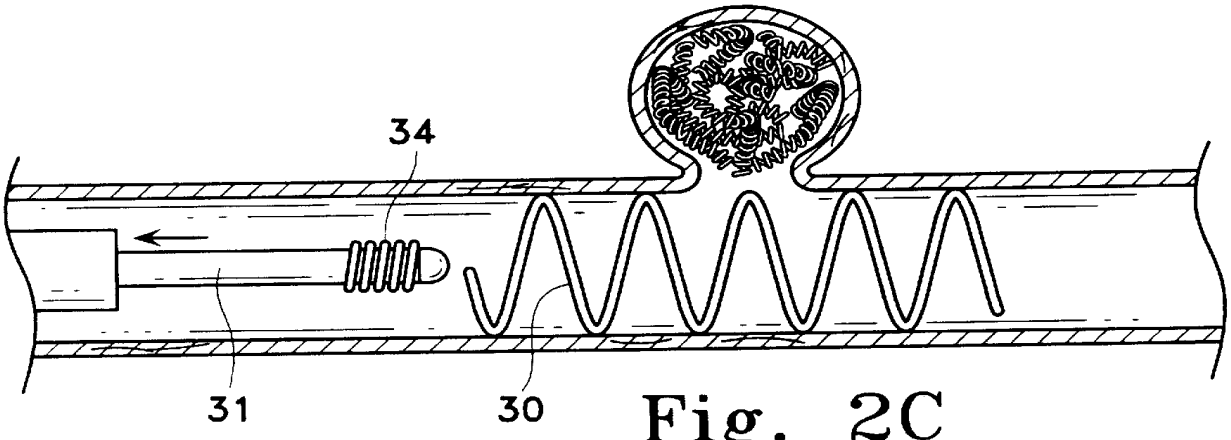


Fig. 2C

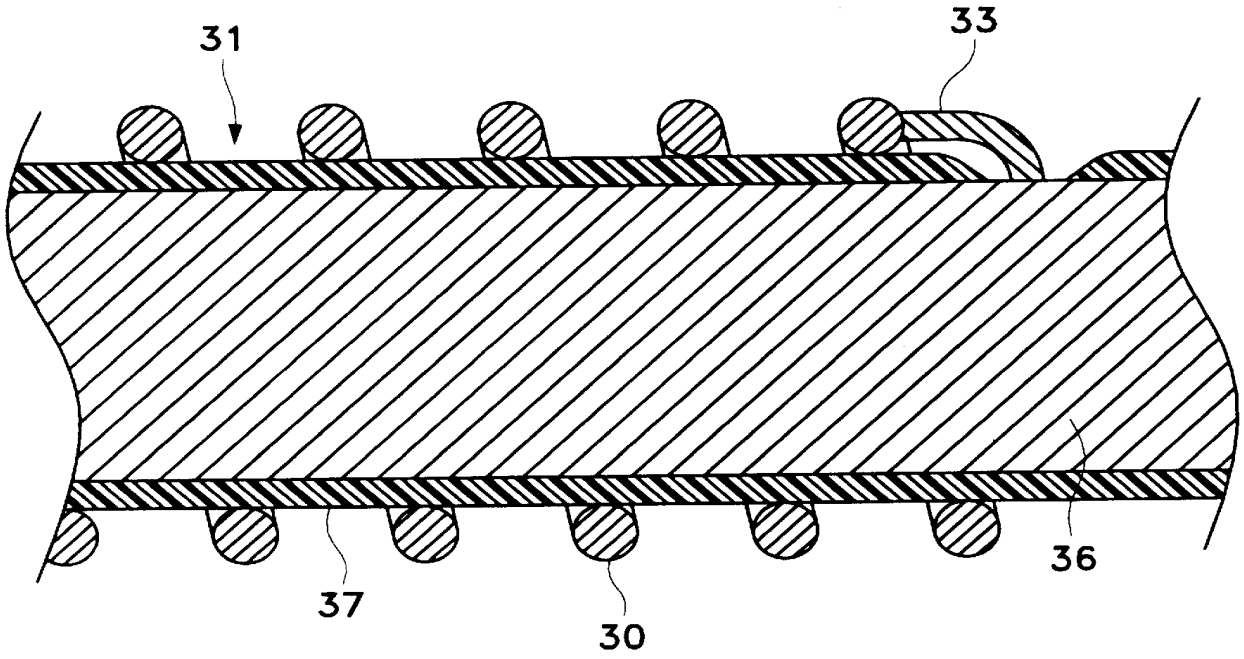


Fig. 3

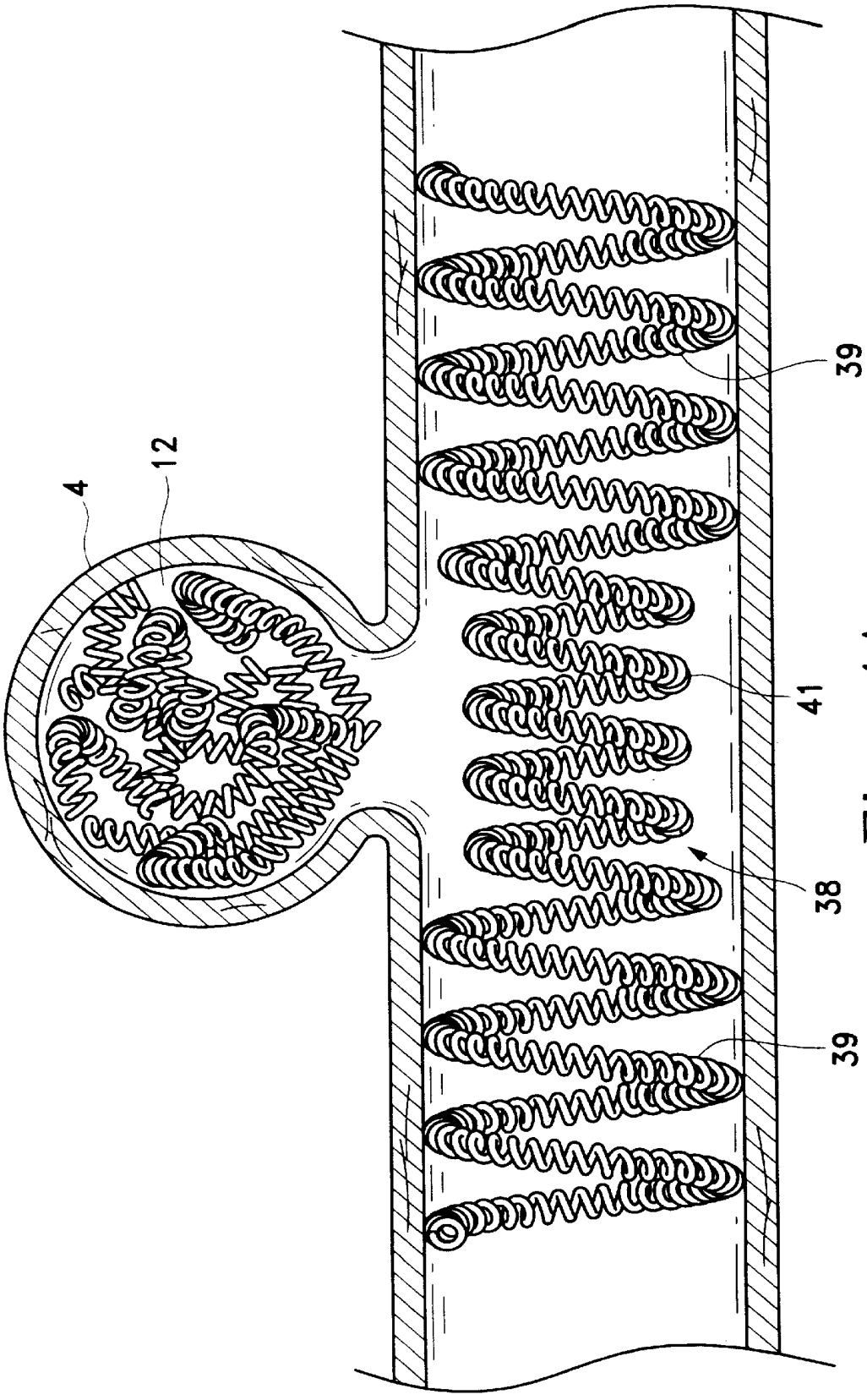


Fig. 4A

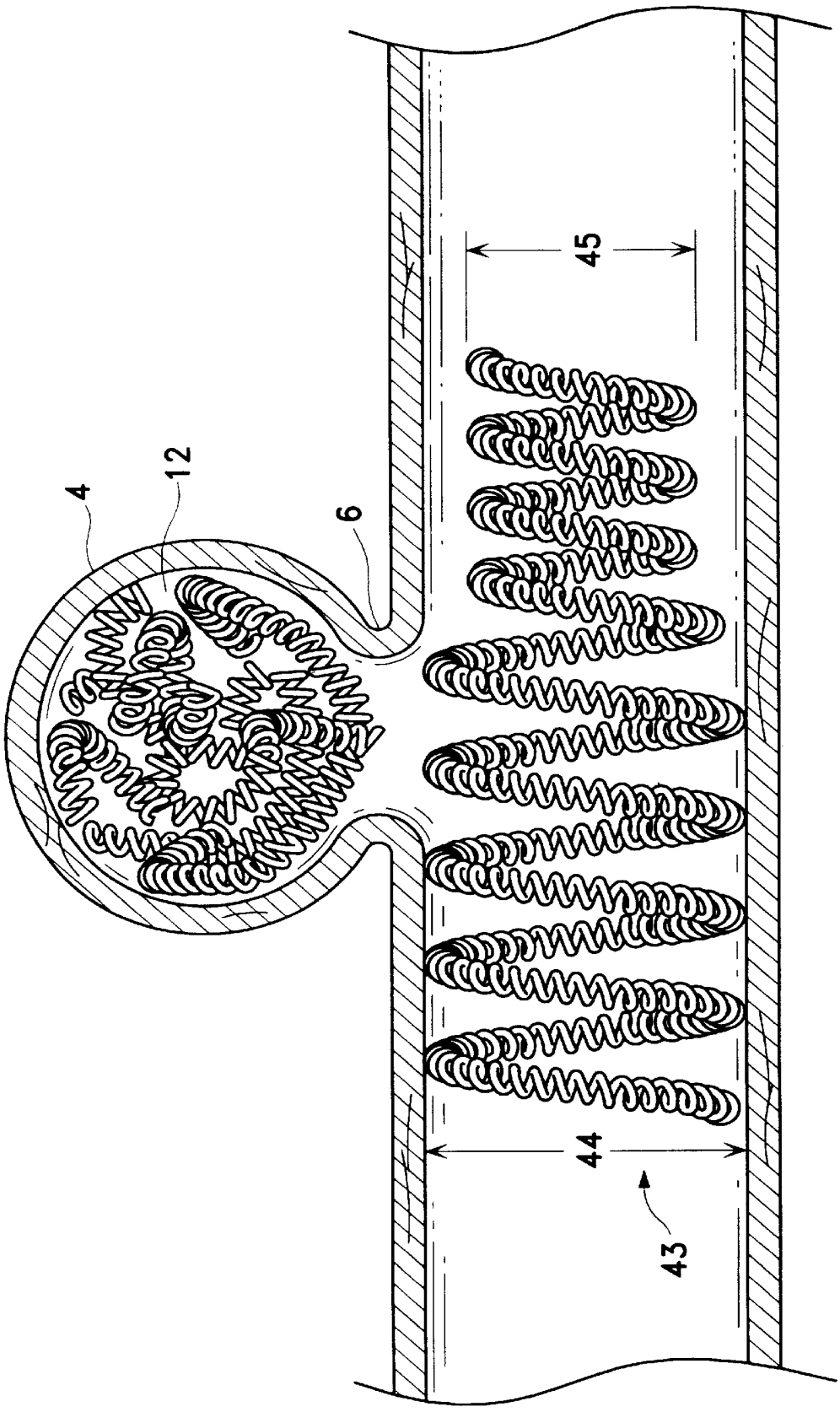


Fig. 4B

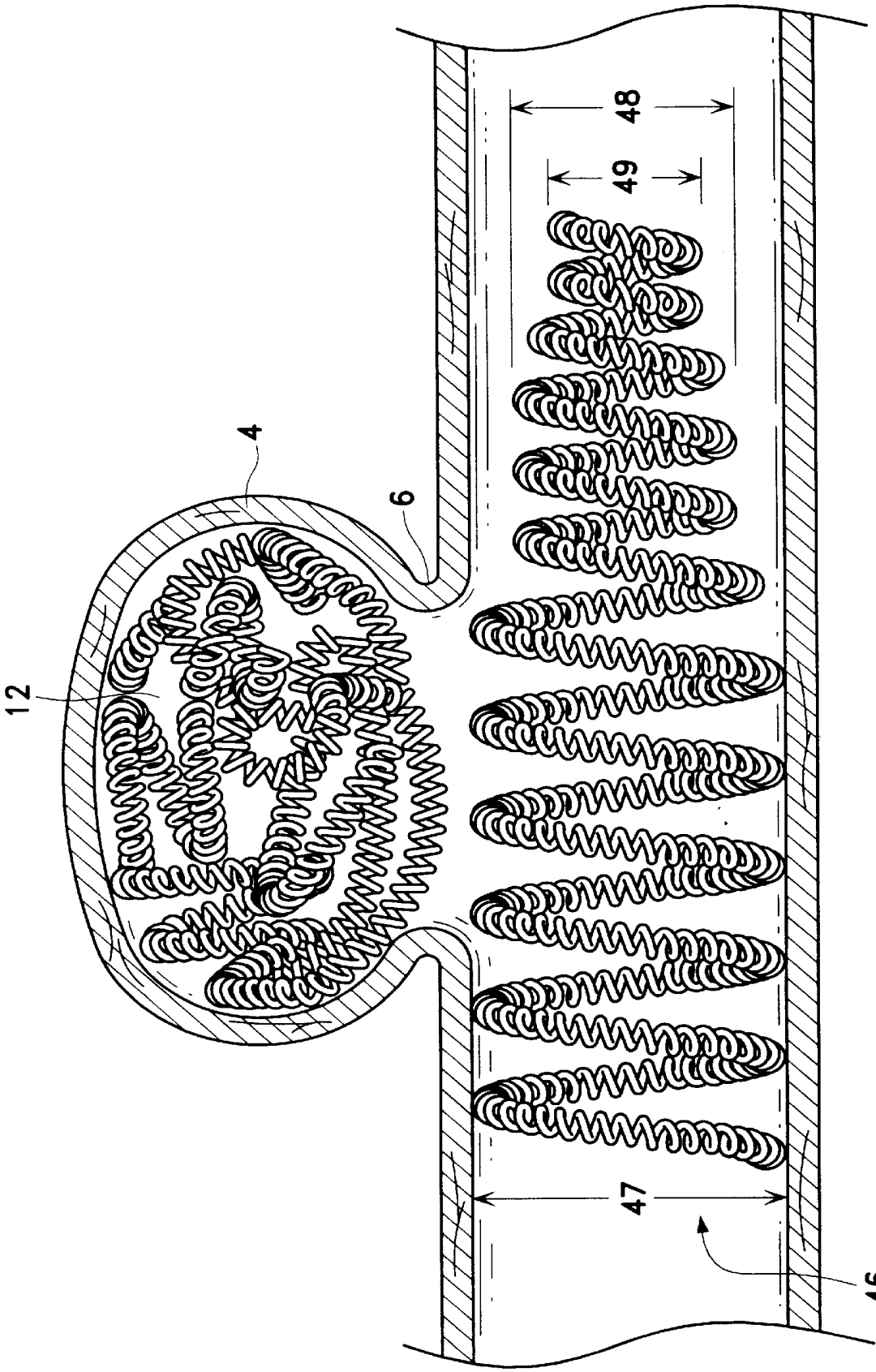


Fig. 4C

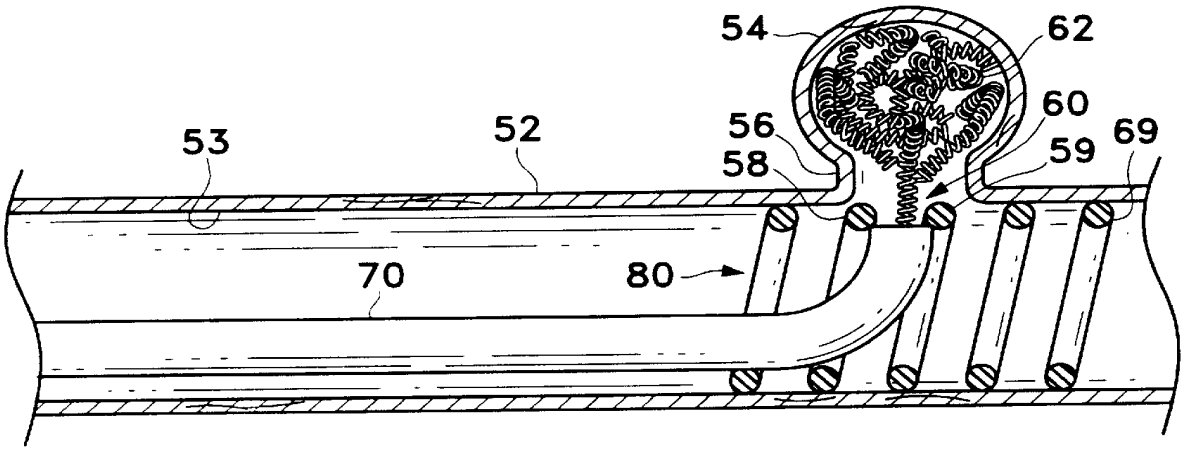


Fig. 5

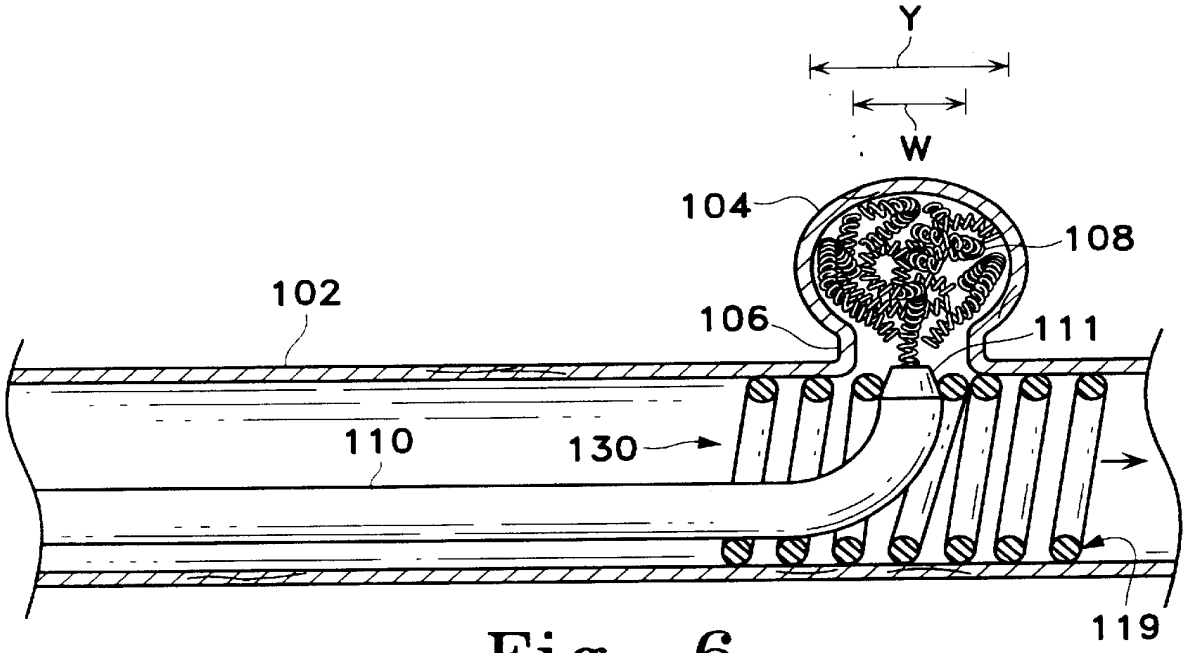


Fig. 6

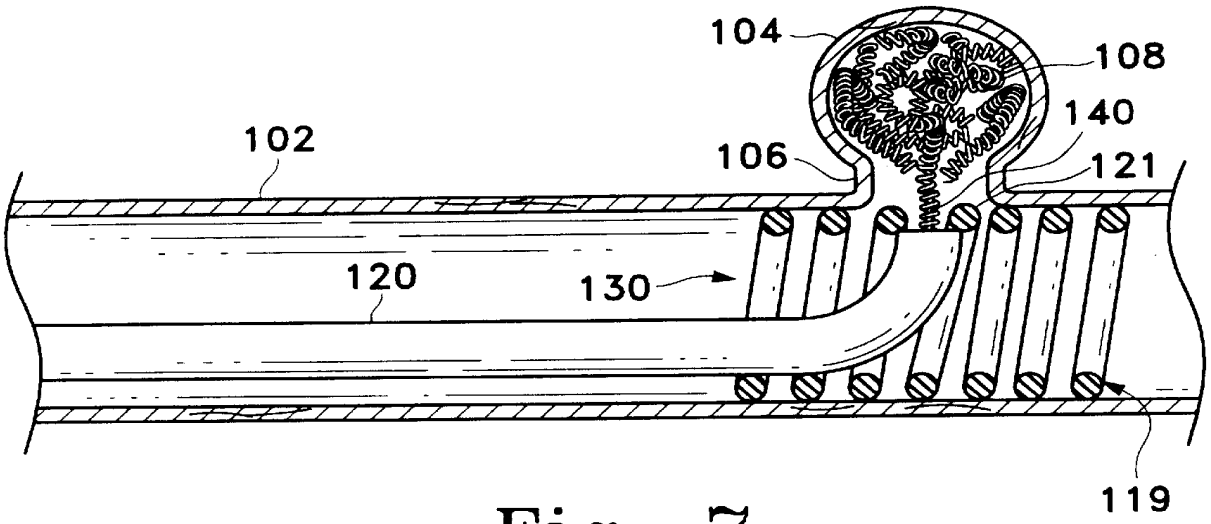


Fig. 7

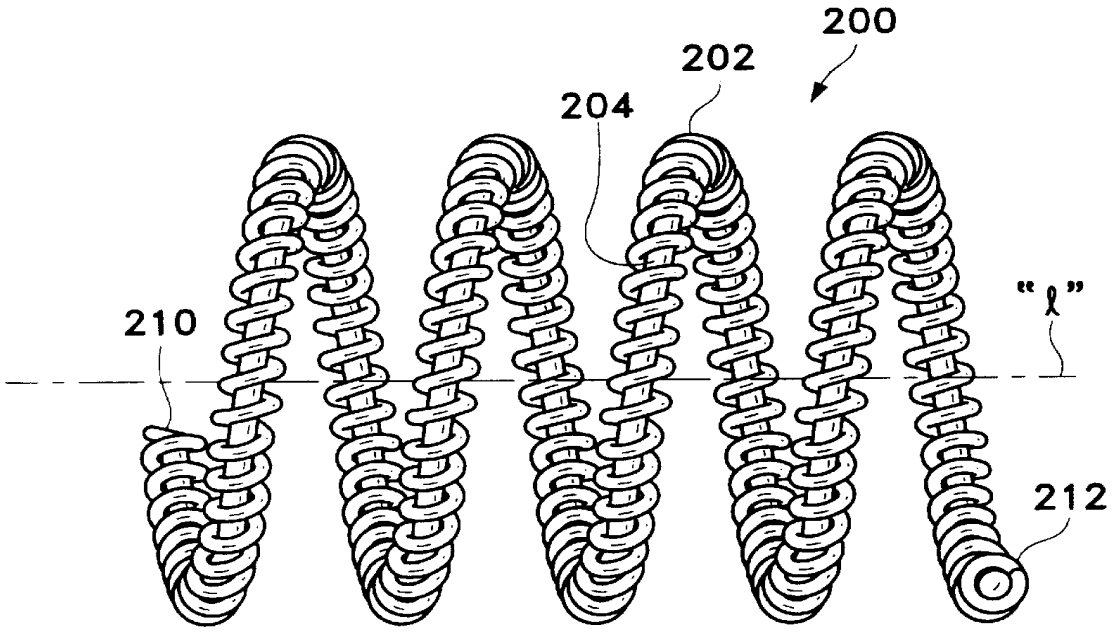


Fig. 8

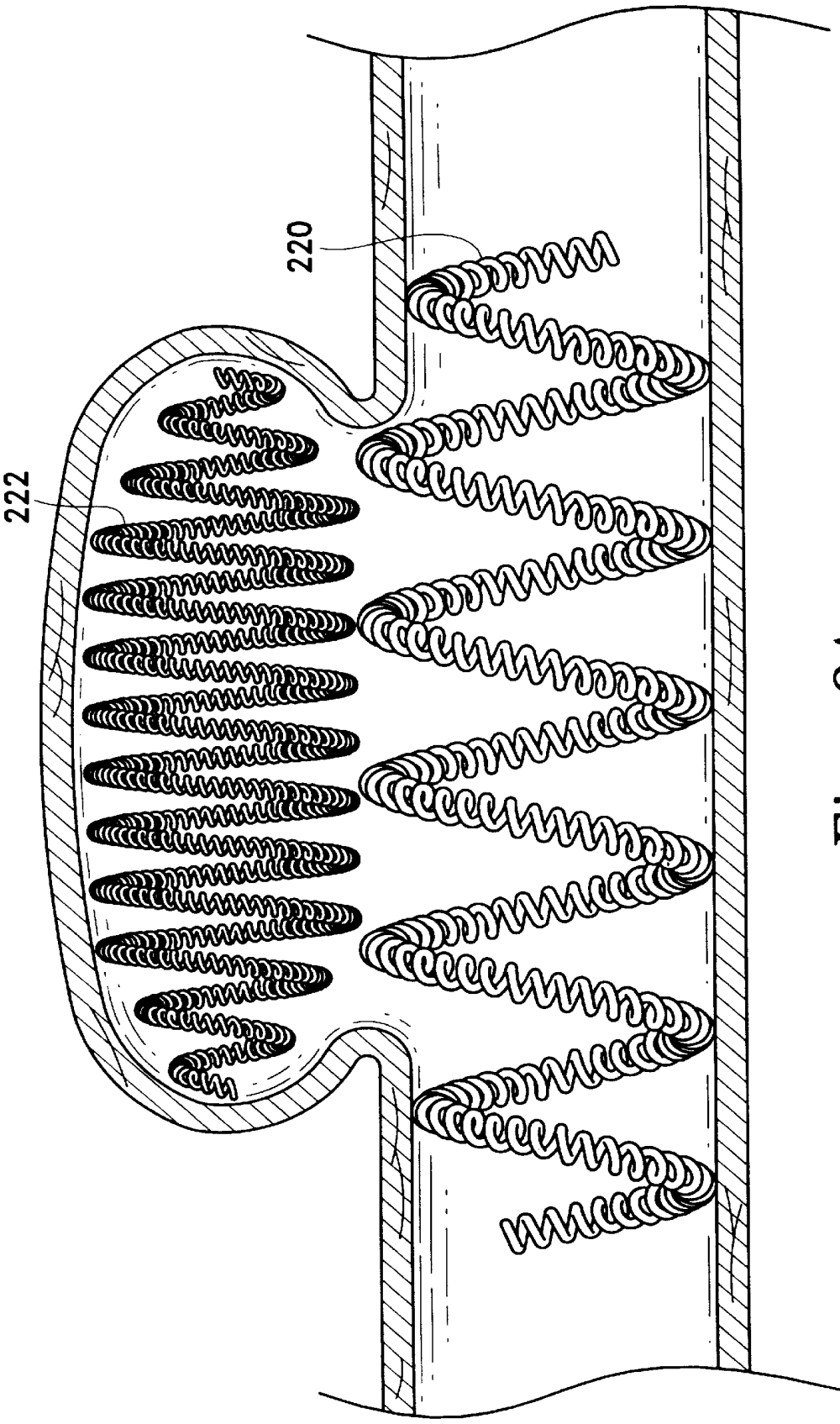


Fig. 9A

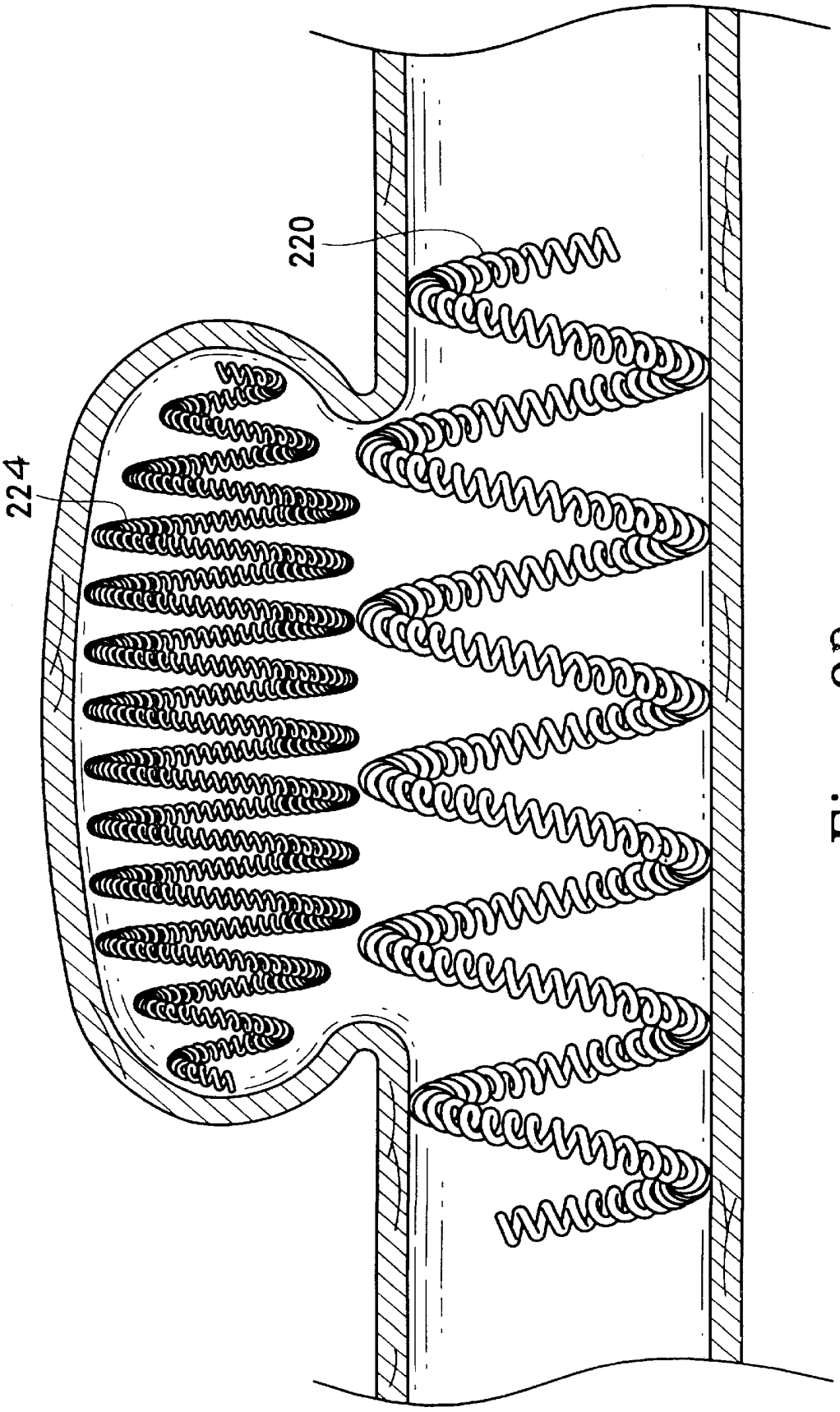


Fig. 9B

ANEURYSM CLOSURE DEVICE ASSEMBLY

FIELD OF THE INVENTION

This invention is an implantable medical device assembly for use in surgical procedures. The invention includes an artificial occlusion kit that uses a retaining device to prevent migration of artificial occlusion implants from an occlusion site, such as an aneurysm, and into an adjacent body space, such as a blood vessel.

BACKGROUND OF THE INVENTION

Different implantable medical devices have been developed for treating various ailments associated with body lumens, such as ailments of body vessel walls or other lumenal walls. One category of implantable medical device that has been developed for artificial occlusion of body spaces is the category of "artificial occlusion devices." Although artificial occlusion devices are useful in occluding body spaces, other applications include occluding body lumens. Examples of lumens that have been identified as candidates for treatment with artificial occlusion devices include, for example, the vas deferens or the fallopian tubes. Most commonly, however, artificial occlusion devices have been disclosed for medical treatment of the vascular lumens and aneurysms in the walls of such vessels. This treatment is commonly referred to as "artificial vaso-occlusion."

Artificial Vaso-occlusion

Artificial vaso-occlusion is a medical treatment that has involved techniques such as the delivery of various occlusive agents including solidifying suspensions, thrombogenic fluids, or emboli such as hog hair or suspensions of metal particles. Delivery of such agents or emboli normally causes a thrombogenic or other occlusive tissue response. Recent advancements in artificial occlusion of vessels and aneurysms have included the delivery and implantation of metal coils. Implantable metal coils that are useful as artificial occlusion devices in vascular lumens or aneurysms are herein referred to as "vaso-occlusion coils."

Vaso-occlusion coils generally are constructed of a wire, usually made of a metal or metal alloy, that is wound into a helix. Vaso-occlusion coils are normally delivered through microcatheters such as the type disclosed in U.S. Pat. No. 4,739,768 to Engelson. The microcatheter commonly tracks a guide wire to a point just proximal of or within the desired site for occlusion. The coil is advanced through the microcatheter and out the distal end hole so to at least partially fill the selected space and create an occlusion.

Once a vaso-occlusion coil is implanted at a desired site, occlusion results either from the space-filling mechanism inherent in the coil itself, or from a cellular response to the coil such as a thrombus formation, or both. The space-filling mechanism of the vaso-occlusion coil may be either based upon a pre-determined secondary geometry, or may be based upon random flow characteristics of the coil as it is expelled from a delivery sheath lumen.

Vaso-occlusion coils have been disclosed that have a secondary geometry or shape which dictates at least in part their space-filling occlusion mechanism. Such a secondary shape may include a secondary helical structure which involves the primary coil helix being itself wound into a second helix. In addition to the space-filling feature, another benefit to having a secondary coil shape is that it may allow the coil readily to anchor itself against the walls of a delivery site. For example, a vaso-occlusion coil having a secondary shape may be ejected from a sheath lumen where it was constrained in a stretched condition to have a first outer diameter equal to the sheath lumen inner diameter. When ejected, the coil passively expands to its secondary shape, often having a larger, second outer diameter to aid in space-filling the body cavity or lumen. This may be an expansion to the coil's relaxed, unrestrained memory state—or at least until the coil encounters a vessel wall against which it exerts a force to complete the anchoring process.

One example of a type of vaso-occlusion coil having a pre-determined secondary shape is described in U.S. Pat. No. 4,994,069 to Ritchart et al. Ritchart describes a vaso-occlusive wire having a memory imparted thereto by heating the wire at about 800° F. for 24 hours after it is shaped. This memory is effective to return the wire from a stretched, linear condition in which it is advanced through a catheter to a space-filling relaxed condition as the wire is released from the catheter. The diameter of the secondary shape is approximately equal to and may be larger than the vessel in which it is deployed.

In contrast to vaso-occlusion coils having pre-determined secondary shapes that dictate in part their space-filling mechanism, other vaso-occlusion coils have been disclosed that take on random shapes when expelled from a delivery sheath. This type of vaso-occlusive coil is often referred to as the "liquid coil." One example of such a vaso-occlusive coil which takes on a random occlusive shape when delivered into a body space is disclosed in pending U.S. patent application Ser. No. 08/413,970, filed Mar. 30, 1995. This document describes very soft and flexible coils which are flow-injectable through the delivery catheter using, e.g., saline solution.

In addition to the various types of space-filling mechanisms and geometries of vaso-occlusion coils, other particularized features of coil designs, such as mechanisms for delivering vaso-occlusion coils through delivery catheters and implanting them in a desired occlusion site, have also been described. Examples of categories of vaso-occlusion coils based upon their delivery mechanisms include pushable coils, mechanically detachable coils, and electrolytically detachable coils.

One example of the type of vaso-occlusion coil referred to as the "pushable coil" is disclosed in U.S. Pat. No. 4,994,069 to Ritchart et al., introduced above. Pushable coils are commonly provided in a cartridge and are pushed or "plunged" from the cartridge into a delivery catheter lumen. A pusher rod advances the pushable coil through and out of the delivery catheter lumen and into the site for occlusion.

In contrast to pushable coils, mechanically detachable vaso-occlusion coils are integrated with a pusher rod and mechanically detached from the pusher after exiting a delivery catheter. Examples of such mechanically detachable vaso-occlusion coils are provided in U.S. Pat. No. 5,261,916 to Engelson, or U.S. Pat. No. 5,250,071 to Palermo.

Further in contrast to the mechanically detachable type of vaso-occlusion coil, the electrolytically detachable type is also integrated with a pusher rod, but is detached from the pusher by applying a direct current that dissolves a sacrificial link between the pusher and the coil. Examples of such electrolytically detachable vaso-occlusion coils are disclosed in U.S. Pat. No. 5,122,136 to Guglielmi, et al, and U.S. Pat. No. 5,354,295 to Guglielmi, et al.

A further improvement upon the electrolytic detachment mechanisms just previously referenced is disclosed in pending U.S. patent application Ser. No. 08/205,512, filed Mar. 3, 1994. This document describes superimposing an alternating current signal over the direct current signal, wherein a sensing circuit monitors the alternating current signal as an indicator of the progression of coil detachment.

Improvements for enhancing the thrombogenic or other occlusive tissue response to metal coils have also been disclosed. For example, vaso-occlusion coils having vaso-occlusive fibers attached thereto have been described (see for example, U.S. Pat. No. 5,226,911 to Chee et al.). A further type of vaso-occlusion coil is used as a detachable dielectric electrode in a radio-frequency artificial vaso-occlusion system, as disclosed in pending U.S. patent application Ser. No. 08/497,507, filed Jun. 30, 1995.

The disclosures of the various patent and pending patent application documents identified in the preceding paragraphs are herein incorporated in their entirety by reference.

Vaso-occlusion Coils in Aneurysms

A wide variety of clinical abnormalities in body lumens may be treated with artificial occlusion methods. For example, artificial occlusion methods have been disclosed for treating feeder vessels into tumors, arterio-venous malformations, fistulas, and aneurysms of vessel walls. Among arterial abnormalities, aneurysms present particular medical risk due to the dangers of potential rupture of the thinned wall inherent in an aneurysm. Occlusion of aneurysms with vaso-occlusion coils without occluding the adjacent artery is a desirable method of reducing such risk.

In one disclosed method of treating aneurysms with vaso-occlusion coils, a microcatheter is initially steered into or adjacent the entrance of an aneurysm, aided by a steerable wire. The wire is then withdrawn from the microcatheter lumen and replaced by the vaso-occlusion coil. The vaso-occlusion coil is advanced through and out of the microcatheter, desirably being completely delivered into the aneurysm. After or during delivery of such a coil into the aneurysm, a portion of the coil might then migrate out of the aneurysm entrance zone and into the feeding vessel. This may cause an undesirable response of occluding the feeding vessel. Also, there is an additional risk that the blood flow may induce movement of the coil farther out of the aneurysm, resulting in a more developed embolus in the good vessel.

One type of aneurysm, commonly referred to as a "wide-neck aneurysm," is known to present particular difficulty in placing and retaining vaso-occlusion coils. Wide-neck aneurysms are herein referred to as aneurysms of vessel walls having a neck or "entrance zone" from the adjacent vessel, which entrance zone has a diameter that either: (1) is at least 80% of the largest diameter of the aneurysm; or (2) is clinically observed to be too wide to effectively retain vaso-occlusion coils that are deployed using conventional techniques.

In attempting to prevent potential migration of vaso-occlusion coils from aneurysms, catheter distal tip shapes may be formed on delivery microcatheters to help support the distal tip during deployment of vaso-occlusive agents. However, this may provide only a partial solution, particularly in the case of wide-neck aneurysms.

There is a need for a retaining device that is adapted to block an entrance zone to an aneurysm such that occlusion devices may be implanted in and retained within the aneurysm and are prevented from migrating through the entrance zone of the aneurysm and into the adjacent vessel.

SUMMARY OF THE INVENTION

This invention is a novel artificial occlusion kit, which includes a novel implantable medical device useful for retaining occlusion devices at an occlusion site, and related method for use. A particularly useful application of the invention is in the treatment of wide-neck aneurysms and aneurysms emanating from a curving vessel.

An artificial occlusion kit is provided for implanting and retaining an artificial occlusion device in a body space adjacent to and extending from a body lumen in a mammal. The artificial occlusion kit has at least one occlusion device adapted for filling at least a portion of the body space, and a retaining device assembly that includes a retaining device.

The retaining device of the artificial occlusion kit is adapted to be delivered and implanted at a retaining site in the body lumen adjacent to the body space to be occluded. This retaining device has a first shape that is radially expandable to a diameter that is sufficient to engage the wall of the body lumen at a retaining site adjacent the body space to be occluded. When engaged with the body lumen wall, the retaining device forms a lumen having a diameter that is sufficient to allow flow therethrough, and also forms a barrier that prevents occlusion devices that are implanted in the body space from migrating out of the body space and into the adjacent body lumen.

In one retaining device variation, the first shape is formed when the retaining device is radially constrained during delivery to the retaining site, and a second shape with an expanded outer diameter is formed when the retaining device is released from radial constraint at the retaining site. Either a coaxial delivery sheath or a coaxial delivery wire may provide this radial constraint. Alternatively, the retaining device may be balloon expandable from the first shape to the second shape.

In another retaining device variation, at least one semi-penetrable space is provided in the barrier formed at the entrance zone into the body space to be occluded. This retaining device may be delivered to the retaining site, followed by introduction of at least one occlusion device into the body space to be occluded through the semi-penetrable space.

In another aspect of the invention, the retaining device may be a metal wire wound into a primary helix that has a secondary geometry which is also a secondary helix. The adjacent windings of the secondary helix may be the semi-penetrable space provided by the appropriate retaining device variation.

In another variation, the semi-penetrable space is sized to allow at least one occlusion device, when radially artificially constrained to a first occlusion device outer diameter, to be inserted therethrough. Subsequent release of the radial constraint on the occlusion device allows it to reconfigure to a second outer diameter which prevents migration back through the semi-penetrable space.

In still a further variation, the semi-penetrable space of the retaining device is distendable. A delivery catheter with a tapered tip may be provided such that the semi-penetrable space is distendable by forcing the delivery catheter tip therethrough and into the body space to be occluded. Alternatively to a tapered-tip delivery catheter, an introducer wire is provided to distend the semi-penetrable spaces of the retaining device. At least one occlusion device is introduced into the body space to be occluded either coaxially through the delivery catheter or over the introducer wire. Subsequent withdrawal of the delivery catheter or introducer wire allows the once distended semi-penetrable space to reform to its original shape, forming a barrier against migration of the occlusion devices out of the occlusion site and into the adjacent lumen.

In a further variation of the artificial occlusion kit, the retaining device is a wire wound into a primary helix over a core member. In a preferred variation of this embodiment, the core member is a metal, preferably a shape-memory

alloy, and most preferably a shape-memory alloy of nickel and titanium. The wire is also preferably a metal, most preferably radiopaque.

Each of the variations discussed herein may further include a smaller diameter "leading helix" in the retaining device to assist in the alignment and deployment of the retaining device as it exits the catheter.

An implantable medical device assembly is also provided, having the structure described for the retaining device of the novel artificial occlusion kit and which is attached to an elongate pusher via a sacrificial link that is electrolytically dissolvable. In one variation, this implantable medical device may take the form of the "wire wound over core member" variation described for the artificial vaso-occlusion kit aspect of the invention.

This invention includes methods for using the apparatus here described.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1A** shows a side view of a vessel with an aneurysm in its wall, wherein a vaso-occlusion coil component of an artificial occlusion kit is shown being delivered into the aneurysm.

FIG. **1B** shows a side view of the vessel and aneurysm of FIG. **1A**, wherein a retaining device assembly of the artificial occlusion kit is shown being delivered to a retaining site in the vessel adjacent the aneurysm which is substantially filled with a plurality of vaso-occlusion coils.

FIG. **1C** shows a side view of the same vessel and aneurysm wherein the retaining device is shown electrolytically detached from a pusher, the retaining device engaging the vessel wall adjacent the entrance zone of the aneurysm, bridging across the entrance zone to form a barrier against vaso-occlusion coil migration into the vessel, and forming a lumen allowing for physiological flow through the vessel.

FIGS. **2A–2C** show in partial section, a side view of an electrolytically deployed device.

FIG. **3** shows in side view cross-section, a portion of the device shown in FIGS. **2A–2C** emphasizing the section of the device employing an electrolytically erodible link.

FIGS. **4A**, **4B**, and **4C** show in partial cut-away, cross-section, variations of the shape of retainers made according to this invention.

FIG. **5** shows a side view of a vessel having in its wall a wide-neck aneurysm, showing a variation of the artificial occlusion kit where the retaining device has a semi-penetrable space through which an artificial occlusion device is being introduced into an aneurysm.

FIG. **6** shows a side view of a vessel having in its wall a wide-neck aneurysm, showing a variation of the artificial occlusion kit where the retaining device has a distensible semi-penetrable space that is shown distended by a delivery catheter through which vaso-occlusion coils are being introduced into the aneurysm.

FIG. **7** shows a side view of the vessel and wide-neck aneurysm, showing a further variation of the assembly shown in FIG. **5**, wherein the distensible semi-penetrable space is shown distended by an introducer wire over which vaso-occlusion coils are being coaxially advanced into the aneurysm.

FIG. **8** shows a perspective view of a further variation of retaining device wherein the retaining device is shown to be constructed of a wire wound into a helix over a core member, the helical wire and core member being formed into a secondary geometry.

FIGS. **9A** and **9B** show in schematic cross-section anatomically shaped filler coils suitable for use in conjunction with the retention devices made according to this invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a novel solution to the problem of vaso-occlusion device migration out of aneurysms or other implantation sites and into the feeding vessels that are not the target of vaso-occlusion. A retaining device is used in a novel artificial occlusion assembly to prevent migration of one or more occlusion devices from a target occlusion site by forming a barrier at the entrance zone to the target site from a feeding vessel. Variations of a novel implantable medical device are provided as the retaining device, which novel implantable medical device is included within the scope of the present invention.

Artificial Occlusion Kit w/Retaining Device

FIGS. **1A–C** show sequential steps of a novel method of occluding a body space—here an aneurysm of a body lumen wall—using one artificial occlusion kit embodiment of the current invention. In this series of Figures, a retaining device is provided in a kit together with at least one vaso-occlusion device, which kit is also shown in use with at least one delivery catheter.

FIG. **1A** shows the first of a plurality of vaso-occlusion coils is shown as it is being implanted into an aneurysm. In FIG. **1B**, a retaining device of a retaining device assembly is shown being delivered to a retaining site in the body lumen adjacent the aneurysm after the aneurysm is substantially occluded with vaso-occlusion coils. In FIG. **1C**, the retaining device is completely implanted at the retaining site and detached from a pusher via electrolytic detachment from a pusher. The implanted retaining device shown forms a barrier against migration of the vaso-occlusion coils from the aneurysm and into the body lumen, while maintaining an open conduit for flow through the body lumen.

In FIG. **1A**, a cut-away side view of a vessel **(2)** having an aneurysm **(4)** in its wall is shown. Vaso-occlusion coil **(8)** is shown being delivered into aneurysm **(4)** out of the distal end of delivery catheter **(10)** in order to occlude the aneurysm **(4)**.

Vaso-occlusion coil **(8)** for the purposes of this invention may be any one of a wide variety of coils that are known in the art for occluding vessels or aneurysms. For example, vaso-occlusion coil **(8)** may be a pushable coil of the type described in U.S. Pat. No. 4,994,069. Or, coil **(8)** may be a mechanically detachable coil such as that described in U.S. Pat. No. 5,261,916 or U.S. Pat. No. 5,250,071. Alternatively, coil **(8)** may be an electrolytically detachable coil such as that described in U.S. Pat. No. 5,122,136 or U.S. Pat. No. 5,354,294.

Still further, vaso-occlusion coil **(8)** may have a preformed secondary shape that is constrained in a stretched orientation when being delivered through delivery catheter **(10)** but reconfigures when delivered beyond delivery catheter **(10)**. Such reconfiguring often includes radial expansion to a relaxed memory state having a desired, pre-determined shaped geometry. Alternatively, coil **(8)** may have highly flexible portions that ball up from random convolutions formed while the coil flows distally during delivery, such as the coils described in pending U.S. patent application Ser. No. 08/413,970, filed Mar. 30, 1995.

The type and geometry of vaso-occlusion coil are normally chosen for the particular delivery mechanism and space-filling characteristics, as may be appropriate for a particular occlusion site. The disclosures of the above ref-

erenced vaso-occlusion coil documents are herein incorporated by reference.

The appropriate design for delivery catheter **(10)** is defined by the ability to reach the desired occlusion site atraumatically and to efficaciously deliver the vaso-occlusion coil into the site as an occlusion implant. One example of a catheter that may be used in the present invention is described in U.S. Pat. No. 4,739,768 to Engelson, the disclosure of which is herein incorporated by reference.

FIG. **1**B shows a retaining device **(19)** being delivered through delivery catheter **(20)** and into vessel **(2)** at the site of aneurysm **(4)**. A plurality of vaso-occlusion coils **(12)** is also shown having been implanted into aneurysm **(4)** prior to delivery of the retaining device **(19)**. Retaining device **(19)** is shown as a distal segment of a retaining device assembly **(15)**, wherein it is attached at its proximal end to a pusher **(16)** which is relatively more stiff than the implantable retaining device **(19)**. Pusher **(16)** is adapted for advancing the retaining device percutaneously through the delivery catheter **(20)**, even when in tortuous bends of the vasculature, into remote internal body spaces for occlusion.

In retaining device assembly **(15)**, retaining device **(19)** and pusher **(16)** are shown to be coupled or attached via ajoint or link **(17)**. The scope of this invention contemplates that retaining device **(19)** and pusher **(16)** can be either electrolytically detachable at link **(17)** or mechanically detachable at link **(17)**. In the electrolytically detachable embodiment, link **(17)** is electrolytically dissolvable when current is applied thereto. Electrolytic detachment mechanisms of the types described in U.S. Pat. No. 5,122,136 or U.S. Pat. No. 5,354,295 may be suitable. In the mechanically detachable embodiment, pusher **(16)** and retaining device **(19)** are mechanically detachably engaged at link **(17)**. In such an assembly, the mechanical detachment mechanisms of the types described in U.S. Pat. No. 5,261,916 or U.S. Pat. No. 5,250,071 may be suitable. The disclosures of these above referenced electrolytically and mechanically detachable coil disclosures are herein incorporated by reference.

It is further contemplated that the use of a retaining device to prevent migration of vaso-occlusion devices from an occlusion site need not be limited to use with a "detachable" pusher-retaining device mechanism as is shown in retaining device assembly **(15)**. It may be equally efficacious, and perhaps even preferred in a given circumstance, to use separate, non-attached retaining device and pusher without the need for a detachable link such as link **(17)**.

Where the pusher is separate and not attached to the retaining device, pushers such as the type described in U.S. Pat. No. 4,994,069 to Ritchart et al. may be satisfactory. In use, the distal end of the pusher can be advanced axially within a delivery catheter lumen to abut a proximal end of the retaining device, also disposed within the delivery lumen. With the distal pusher end in confronting engagement with the retaining device proximal end, further advancement of the pusher by the user will effectively push the retaining device distally through the lumen, out of the delivery catheter from a distal port thereof, and into a vessel site adjacent a body space where occlusion devices are deployed.

In the artificial occlusion kit variation of FIG. **1**B, retaining device **(19)** has a memory in the form of a predetermined, shaped, secondary geometry. Retaining device **(19)** is shown to have a first shape with a first outer diameter "A" where it is positioned within delivery catheter **(20)**. The delivery lumen **(22)**, which ends distally in distal delivery port **(23)**, radially constrains the retaining device such that the first outer diameter is defined by the delivery lumen **(22)** inner diameter. When released from a radially constraining condition, retaining device **(19)** also forms a second shape with a second outer diameter greater than the first outer diameter "A." and sufficient to engage the vessel wall. In FIG. **1**B, retaining device **(19)** is shown extending beyond the distal delivery port of the delivery lumen **(22)** where it is radially artificially unconstrained and expanded to an outer diameter "B" larger than the first diameter "A," engaging the lumen wall at the retaining site adjacent the aneurysm.

It is contemplated that the completely relaxed, unconstrained second outer diameter of the retaining device may be slightly greater than the diameter of the vessel. This may be necessary in order to maintain accurate placement of the retaining device in the vessel lumen at the aneurysm site. However, the purpose of the retaining device is merely to form a barrier at the entrance zone of the aneurysm to prevent occlusion coil migration. Unnecessary trauma to the vessel wall, such as from oversizing or coil designs that are too stiff to perform the stated purpose should be avoided.

Retaining device **(19)** is shown in FIG. **1**B to have a helical geometry. In one preferred embodiment, retaining device **(19)** is a metal wire that is wound into a primary helix, shown in FIG. **1**B having a primary helix diameter "C". This primary helix is preferably pre-formed into a secondary geometry that, as shown for this embodiment, is also in the form of a secondary helix. Therefore, the first and second shapes and corresponding first and second outer diameters that the retaining device takes when being delivered to and implanted in the vessel, respectively, are defined by the secondary geometry of the retaining device. These shapes are formed about a longitudinal axis, shown in FIG. **1**B at "L," and their respective outer diameters are defined on a radial plane perpendicular to that axis.

Retaining device **(19)** is also shown in FIG. **1**B to form a lumen **(30)**. In this embodiment, lumen **(30)** is defined by the simple helical shape of the retaining device's secondary geometry and extends along the longitudinal axis "L" of that helix. It is contemplated that first and second shapes other than a simple helix may still fall within the scope of the present invention. However, the purpose of the retaining device is to form a barrier at the entrance zone to the body space being artificially occluded by occlusion devices. Occlusion of the body lumen adjacent to the occlusion site is to be avoided in the use of the present invention. It is therefore an important aspect of the present invention that there be a physiologically acceptable through-lumen formed by the retaining device when implanted into the body lumen.

In the artificial occlusion kit embodiment of FIG. **1**B, delivery catheter **(10)** may be the same catheter as that used for delivering the occlusion devices, such as delivery catheter **(10)** in FIG. **1**A. Or, the two delivery catheters may in certain circumstances have different required characteristics for delivering the occlusion devices and retaining devices, respectively. For instance, a desired tip shape for delivering the occlusion devices into an aneurysm radially at the vessel wall may be different than the tip shape appropriate for delivering the retaining device transversely into the vessel lumen adjacent the aneurysm. Similarly, the retaining device and the occluding devices are characteristically of different designs, since one's function is to substantially space fill and the other's is to form a barrier at the aneurysm and also to keep the vessel lumen open. Thus, the delivery catheters for the two designs may require different delivery lumen diameters, material construction, etc. as may be appropriate according to one of ordinary skill.

The current invention further contemplates radially expandable retaining device assemblies other than the type that is delivered through a radially confining sheath. For instance, a delivery wire may provide a coaxial rail over which a retaining device may be advanced such as by a pusher located proximally of the retaining device. In such an assembly, the retaining device may have a lumen that coaxially tracks the delivery wire, the delivery wire providing radial constraint on the retaining device to form the first radially constrained shape. Advancing the retaining device distally past the end of the delivery wire releases the radial constraint and allows the retaining device to expand to a second shape.

Alternatively, a further retaining device variation may be delivered upon and expanded by a balloon on the distal end of a balloon catheter. In such a variation, the retaining device is provided for delivery to the retaining site while it is formed in its first shape coaxially engaged over a balloon in a deflated state. Once at the retaining site, inflation of the balloon radially expands the retaining device into a second shape having an outer diameter sufficient to engage the vessel wall and which forms a barrier across the entrance zone to an aneurysm. Subsequent deflation and withdrawal of the balloon leaves the radially expanded retaining device implanted at the retaining site, which retaining device forms a lumen where the expanded balloon once was.

Electrolytically Detachable Retaining Device

In FIG. **1**C, a particular retaining device variation is shown detached at the retaining site in vessel **(2)** that is adjacent to a body space to be occluded, here aneurysm **(4)**. Retaining device **(19)** is shown having a shape that is expanded along its length to a diameter sufficient to engage the vessel wall at regions adjacent an entrance zone **(6)** to aneurysm **(4)**. Retaining device **(19)** also bridges across entrance zone **(6)** and forms a barrier against any of the plurality of vaso-occlusion devices **(12)** from migrating out of the aneurysm and into vessel **(2)**.

In the embodiment shown in FIG. **1**C, retaining device **(19)** has been detached from pusher **(16)** by means of electrolytic or erosive severing of link **(17)**. As mentioned earlier, such electrolytic detachment may occur via the systems and methods as described in U.S. Pat. No. 5,122,136; U.S. Pat. No. 5,354,294; or co-pending U.S. patent application Ser. No. 08/499,525, filed on Jul. 7, 1995, as may be apparent to one of ordinary skill in the art. The disclosures of these documents have previously been incorporated by reference. Much different from those disclosures, however, is the fact that the retaining device of the current invention is not an occlusion device and must provide a through-lumen for flow when implanted into a vessel lumen (in fact the opposite function of the previously disclosed electrolytically detachable occlusion devices).

Briefly, however, power source "E" is electrically coupled to electrolytically severable link **(17)**. An electrode **(40)** is also shown schematically in FIG. **1**C, where it is also shown electrically coupled with power source "E." Electrode **(40)** may be a skin electrode having a relatively high surface area in contact with the patient when compared to that of link **(17)**.

In clinical use, retaining device assembly **(15)** is disposed within the body such that link **(17)** is in patient contact. Since electrode **(40)** is in skin contact with the patient, a circuit may be formed wherein direct current from power source "E" may pass through link **(17)**, quickly dissipate at a low current density through the patient as an electrical conductor, and through electrode **(40)** back to power source "E." This current serves to dissolve link **(17)** until retaining device **(19)** is detached from pusher **(16)**.

Power source "E" may additionally superimpose an alternating current over the direct current signal, which alternating current signal may be sensed by a sensing circuit (not shown) as an indicator of the progression of electrolytic detachment at link **(17)**. Additionally, a control circuit (not shown) may be used to alter the output power signal or shut the signal off upon the sensing of a critical parameter by the sensing circuit, such as the sensing of a particular change in the alternating current component of the output signal. Such monitoring and feedback control of electrolytic detachment may employ the apparatus and methods as described in co-pending U.S. patent application Ser.No. 08/205,512 filed Mar. 3, 1994 (previously discussed).

In the artificial occlusion kit embodiments described, cross sectional intrusion into the vessel lumen where implanted should be kept to a minimum. Beneficially to this invention, the electrolytic detachment allows for minimal engaging structure at the detachable coupling end of the implantable medical device (as compared to mechanically detachable designs which may require clasps, enlarged balls, etc. on the end of the implant coil). It is believed, therefore, that electrolytic dissolution of link **(17)** thus provides an optimal solution for implanting an implantable medical device for use as an occlusion coil retaining device.

FIGS. **2**A–**2**C depict a different variation of the artificial occlusion kit. In this variation, a vaso-occlusive coil **(12)** is maintained in an aneurysm **(4)** emanating from an artery **(2)** by a retaining device assembly **(30)** which is delivered to the site of the aneurysm **(4)** by guidewire. The retaining device assembly **(30)** is maintained in a radially compressed fashion by the use of a pair of electrolytic links **(32, 33)**. As will be shown below in discussion of FIG. **3**.

FIG. **2**A shows the retaining device assembly **(30)** closely coiled to the body of the core or guidewire **(31)**. Preferably, the retaining device assembly **(30)** is of a material or has been treated in such a way that the "normal" or relaxed condition of the retaining device assembly **(30)** is as shown in FIG. **2**C. A single wire device is depicted in FIGS. **2**A, **2**B and **2**C, but a helically wound coil is certainly suitable as well. In the variation shown in these figures, the retaining device assembly **(30)** must be either insulated in its entirety from the surrounding fluid (via, e.g., a plastic coating or the like) or of a material which is more noble or higher in the electromotive series than are the links **(32)** and **(33)** shown in the drawing. Further, the guidewire **(31)** distal tip coil **(34)** and the like must be insulated as well. As was discussed above in some detail, this detachment link operates via the electrolytic erosion of the bare links found at **(32)** and **(33)**. In the sequence shown in FIGS. **2**A, **2**B and **2**C, the link found at **(33)** is smaller in diameter than is the link found at **(32)**. In this way, as current is applied to core wire **(31)** and passes from that core wire into the links **(32)** and **(33)**, link **(33)** erodes to a point where it breaks earlier than does the link at **(32)** simply because of the smaller diameter of link **(33)**.

Once link **(33)** has disintegrated as is shown in FIG. **2**B, link **(32)** continues to electrolytically erode as time passes. After the second joint **(32)** has broken and the retaining device assembly **(30)** has expanded as shown in FIG. **2**C, the core wire and its allied parts **(31)** are removed.

FIG. **3** shows a portion of the core wire **(31)** with the retaining device assembly **(30)** closely disposed on its outer surface as would be the case in FIG. **2**A. In this close up arrangement, the inner core **(36)** is covered by an insulating layer **(37)** of, e.g., a polytetrafluoroethylene. The displayed link **(33)** is in an electrical contact with the core **(36)** and holds the retaining device assembly **(30)** in close contact

with the core wire assembly (31). It is this link (33) which erodes to release the retaining device assembly (30).

FIG. 4A shows a variation of the overall shape of a retaining device assembly (38) made in keeping with this invention. In particular, the retaining device assembly (38) has two end regions (39) which have a diameter when deployed which approximates (or is slightly larger than) the inner diameter of the vessel lumen into which it is placed. The retaining device assembly (38) has a center section (41) which has a smaller overall radius than the two end sections (39). The smaller mid-section (41) has a variety of benefits. For instance, it does not press on the vessel or on the coil (12) within aneurysm (4). Yet it is sufficiently close to the mouth of aneurysm (4) to prevent coil (12) from migrating to other parts of the body. The retaining device assembly (38) made in this form is easier to move should it be mal-placed in the human body. It has smaller regions in contact with the vessel lumen.

The shape of the device is not particularly critical in many of these variations. The shape of retaining device assembly (38) must be sufficiently appropriate for it to maintain the coil (12) within aneurysm (14). It must have sufficient radial springiness to allow its shape to be maintained in the lumen of the body vessel described herein.

We have found that, on occasion, the retaining devices shown in the Figures will not achieve the desirable generally cylindrical shape found in those Figures. This problem can be alleviated in a variety of ways. A careful user will find it possible to twist the catheter during the initial ejection of a couple of turns of the retaining device assembly to maintain the device in the proper orientation in the lumen. Some users will find that the use of a catheter distal tip having a turn will help in deployment f the retainer. One very effective and highly desirable method of preventing the retainer from turning in the vessel lumen during deployment is found in FIGS. 4B and 4C. In this variation of the invention, the retaining device assembly (43 in FIG. 4B and 46 in FIG. 4C), incorporates a leading or distal helix section which has a deployed diameter which is smaller than the diameter of the vessel lumen.

In FIG. 4B, the retaining device assembly (43) is first deployed to the right (or distal end) of the Figure. The proximal end of the retaining device assembly has a diameter (44) which is equal to or larger than the diameter of the vessel lumen. the earlier deployed distal end has a smaller diameter (45). during deployment of the device, the smaller diameter distal section exits the catheter end and simply forms a tubular cylinder within the lumen of the vessel. The distal end of the retainer device assembly (43) conceptually forms an indexing end and aligns the remainder of the retainer device assembly (43) with the lumen for further deployment. The distal diameter (45) should not be appreciably smaller than the lumen diameter (44) lest the retaining device assembly (43) begin to block blood flow. We believe that the distal diameter (45) should be at least 75% of the lumen diameter (44).

It should also be noted that the proximal diameter portion of the retaining device assembly (43) does not completely cover the mouth (6) of the aneurysm (4) in the Figures. This is not critical but the is an option in this variation.

FIG. 4C shows a similar variation of the invention in which the distal portion of the retaining device assembly (46) is stepped and has two short sections of respectively smaller diameters (48,49).

Semi-Penetrable Retaining Device

A further artificial occlusion kit embodiment allows for implantation of the retaining device prior to implantation of occlusion devices, an embodiment particularly useful in "wide-neck" aneurysms. In artificially occluding these types of body spaces using conventional systems, occlusion devices may not be implantable at all into the aneurysm without immediate migration into a flowing vessel prior to insertion of a retaining device at the entrance zone. This embodiment solves this problem by providing semi-penetrable spaces in the retaining device at the entrance zone from the body lumen to the adjacent body space to be occluded.

As is shown in FIGS. 5–7, the retaining device in the variations of this embodiment may be a helically wound member, wherein the semi-penetrable space for occlusion device insertion is provided by the space between adjacent windings of the helix. In a preferred mode, the helically wound member that forms the retaining device is a metal wire wound into a primary helix which is further wound into a secondary helix. In this mode, windings of the secondary helix form the semi-penetrable space for occlusion device insertion.

In the variation shown in FIG. 5, the pre-determined, semi-penetrable space (60) of retaining device (69) is defined by the space between adjacent helical windings (58) and (59). This semi-penetrable space (60) is equal to or greater in diameter than occlusion device (62) when it is being introduced into aneurysm (54). However, semi-penetrable space (60) is less than the diameter of occlusion device (62) after it is in the aneurysm. Thus, in this embodiment, the spacing provided by the retaining device allows the introduction of occlusion devices into the aneurysm but does not allow significant migration of occlusion devices, once implanted, back into the adjacent vessel lumen (53).

More particularly, in FIG. 5 the occlusion device (62) is radially constrained to a first shape having a first outer diameter when within the delivery lumen of delivery catheter (70). The delivery catheter distal end is abutting the inner surface of the retaining device (69). The occlusion device (62) is then advanced out the distal end of the delivery catheter (70) and through the space in the retaining device (69), where it is then radially artificially unconstrained. Once released into the aneurysm sac through the retaining device semi-penetrable space, the occlusion device (62) takes on a second shape having a second outer diameter that prevents it from migrating back through the semi-penetrable space and into the body lumen (53).

In a more particular embodiment of the artificial occlusion kit shown in FIG. 5, the semi-penetrable spaces of the retaining device are distensible. This distensibility enhances the semi-penetrability of the spaces. More specifically, occlusion devices may be introduced through such spaces when an applied force distends open the spaces. Once the occlusion devices are implanted into the occlusion site, however, passive migration of the devices back through the spaces does not provide the requisite force to distend open these spaces—the passive migration is thus prevented.

In one aspect of this variation, a particular occlusion device may be used in conjunction with a retaining device, and be of such construction and dimension that it may be advanced unaided through the spaces provided in the retaining device. For example, detachable occlusion devices such as those described in U.S. Pat. No. 5,122,136 or U.S. Pat. No. 5,354,295 may be constructed with sufficient pushability to be advanced between adjacent coil winds of the retaining device and into the aneurysm sac. They may thereafter be detached within the aneurysm for occlusion.

Another aspect of this variation is shown in FIG. 6. Here, retaining device (119) is shown implanted into vessel (102)

such that it radially engages the vessel wall adjacent to entrance zone (106) to wide-neck aneurysm (104) and bridges across entrance zone (106). The helical shape of retaining device (119) is shown to have a pre-determined spacing which may be spread when adjacent helical windings are forced apart. In FIG. 6, delivery catheter (110) is advanced through the retaining device and into the entrance zone (106) of the aneurysm (104).

In the particular variation of FIG. 6, delivery catheter (110) has a tip (111) which is tapered and dimensioned such that adjacent helical windings of retaining device (119) are forced apart when delivery catheter (110) is forced radially against the retaining device (119) from its inner lumen (130) and toward the entrance zone (106). To achieve this interaction, delivery catheter (110) may, for example, have a pre-shaped bend in the distal delivery catheter region ending in tip (111). This shape may aid in the advancement of the delivery catheter through the branching vasculature, or may also be sufficiently straightened coaxially over a guidewire to avoid proximal vessel trauma while tracking to the site.

In a further variation shown in FIG. 7, an introducer wire (140) may be forced through spaces provided in the retaining device, such as between adjacent winds of a helically shaped retaining device as shown in FIG. 7. Once the introducer wire (140) is advanced through the retaining device and into the aneurysm, a delivery catheter such as delivery catheter (110) (shown in FIG. 6) may thereafter be advanced coaxially over the introducer wire (140) and into the entrance zone of the wide-neck aneurysm. An advantage to using an introducer wire in this technique as compared to that previously described in reference to FIG. 6 is that the delivery catheter may be introduced into the aneurysm over the introducer without the need for preshaping the delivery catheter.

In the particular variation of FIG. 7, however, delivery catheter (120) is not shown to be advanced into entrance zone (106) or aneurysm (104), but rather is advanced merely to abut the inner diameter of the helical windings forming retaining device (119). Vaso-occlusion coil (108) is shown being advanced coaxially over introducer wire (140) while advancing through delivery catheter (120), through adjacent windings of helical retaining device (119), and ultimately off the distal end of introducer wire (140) and into the sac of aneurysm (104). Such coaxial advancement of vaso-occlusion coil (108) may occur, for example, by coaxially advancing a pusher member, located proximally of vaso-occlusion coil (108), in the distal direction against a proximal end of vaso-occlusion coil.

The critical performance of the introducer wire is that it must be sufficiently stiff and of such diameter and geometry to allow it to pass through the spacing provided in the retaining device (119). However, it should also not be too stiff so as to present risk of trauma or perforation of the thinned aneurysm wall. Such introducer wire (140) may also be shapeable such that it is adapted for tracking to the retaining site adjacent the aneurysm, as well as for advancing through the spaces in the retaining device barrier at the aneurysm entrance zone. Conventional guidewires of the type known in the art may perform sufficiently as introducer wire (140) in a particular case. Alternatively, the present invention further contemplates obvious alterations to known wire designs in order to function with the individual features of a particular retaining device design, as may be apparent to one of ordinary skill. Such particularized retaining device features that may dictate introducer wire design parameters, for example, may be the diameter and degree of distensibility of the semi-permeable space.

"Coil Over Core" Retaining Device

A further embodiment of the present invention is shown in FIG. 8. In this variation, the implantable medical device that functions as a retaining device in the novel artificial occlusion kit has a particular construction that includes a wire (202) wound into a primary helix over an inner core member (204). The inner core member (204) and primary wire helix are also wound into a secondary geometry, and are soldered or welded at both of two ends (210) and (212). The secured ends (210) and (212) serve to secure the "wire over core" composite relationship and also provide smooth ends for safety considerations in this implantable device.

Preferably, the inner core member (204) is a metal mandrel, and more preferably is a superelastic alloy of nickel-titanium. In one particular variation, the inner core member (204) is constructed of a nickel-titanium alloy and has an outer diameter from 0.003" to 0.006". The helically wound wire (202) in this preferred variation may be a radiopaque metal, such as platinum, gold, or tungsten, and has an outer diameter in the range of 0.001" to 0.006". The coil may have 0–100% spacing. Preferably, wire (202) is wound at a pitch of 0.001" to 0.008" with 0–100% spacing. For instance, a coil made with 0.003" wire with 0.006" pitch has 100% spacing; a coil with 0.003" wire and 0.006" pitch has 0% spacing.

In this variation, wire (202) is secured to the inner core member (204) using the following process: the coil is secured to the inner core member at least two or several locations, preferably at both ends. One method for joining the components involves resistance welding or a similar such process. Soldering or brazing is similarly useful in joining the metals.

In the "wire over core" combination structure such as that just described, the inner core member (204) is chosen such as to provide the requisite shape memory and stiffness. This inner core member may not by itself provide optimal radiopacity, since it is not chosen for that purpose. The requisite radiopacity of the device may instead be provided by the outer wound coil (202), which might not provide optimal stiffness or material memory if it were only available alone in the device. It is believed that the combined features of this "wire over core" design may optimally adapt prior known implantable coil technologies to meet the particular structural needs of a retaining device in the current invention.

For instance, it is important that the elongate retaining device be flexible along its length so that it can be implanted into lumens having bends. However, it is believed that too much flexibility may correspond to irregular and random conformations of the coil when implanted in-vivo, which may produce an occlusive effect. A primary helical coil wound into a secondary helix, without more, may be too flexible to effectively engage a vessel wall along the requisite length to form a barrier against occlusion device migration. However, the addition of the mandrel in what would otherwise be the primary helix lumen provides a stiffening structure that still allows for a certain controlled flexibility of the secondary helical shape.

Additionally, prior vaso-occlusion coils require substantial space filling for effective cross-sectional blockage of a body lumen, for example. In these devices, only a minimal portion of the device may be required to actually radially engage a vessel wall for primarily the purpose of anchoring the device at the occlusion site. This means only a small portion of the coil may need to reconfigure from a first constrained diameter during delivery to a second diameter at least approximating the lumenal wall diameter when deliv-

ered. It may be acceptable, even desirable, for such occlusion coils to have portions not so significantly altered in their cross-sectional diameter when they are delivered at an implantation site, so long as their shape presents an occlusion to flow.

In contrast, the present inventive retaining device must take on a shape at the retaining site that has sufficient outer diameter along a sufficient length of the device to form an effective barrier across the aneurysm entrance zone at the vessel wall. Impinging into the lumen's cross-section is generally undesirable. The reconfiguration to this expanded shape from a first radially constrained shape during delivery may correspond to a higher degree of requisite material memory than is possible from a simple fine wire wound into the primary and secondary helix shapes as previously disclosed. An inner core mandrel, however, may offer the structure necessary to provide such memory.

In another particular retaining device variation, the wire forming the primary helical core is wound much tighter than a similar wire might be wound to optimally form an occlusion device. It is believed that coil stiffness may be controlled by adjusting the outer diameter of the primary coil helix (e.g. tightness of winding) to which a given wire is wound. It is believed that, by providing one preferred retaining device may comprise a wire wound very tightly into a primary helix that has also a secondary shape.

One preferred application of this "tightly wound" variation comprises a platinum wire of 0.005" outer diameter wound over a 0.009" mandrel. In contrast, common known occlusion coils for occluding aneurysms is constructed a 0.005" wire wound over a 0.011" mandrel. Similarly, when a smaller diameter primary helix is desired, a wire having an outer diameter of 0.003" may be wound over a mandrel having an outer diameter of 0.007". In any case, the wire is thereafter annealed in the wound shape to form a primary coil of pre-determined dimensions. A secondary shape may then be imparted to the primary coil, which secondary shape may also be a helical coil.

It should be apparent to those skilled in this art that the coil placed within an aneurysm need not be the random shape described and shown above. Indeed, many shapes would be suitable for use with this invention. We have found that anatomically shaped oval **(222)** or semi-oval **(224)** coils are suitable for this invention. It should be apparent that both these are regularly wound and are provided with the shape of the anatomical cavity into which they are placed. Coils **(222)** and **(224)** provide a similar amount a rate of occlusion within the aneurysm structure and yet do so with a significantly smaller mass of coil than the random shapes shown above in many of the drawings.

Other Clinical Applications and Design Embodiments

The ultimate goal of the particular artificial occlusion kits, novel components thereof, and related methods described above is to occlude aneurysms having entrance zones or necks that are of such width and geometry that conventional techniques would result in unwanted migration of occlusion devices from the aneurysm and into the adjacent vessel. However, the assemblies, components, and methods of the present invention that were conceived of in order to meet this need may provide additional benefits in other medical treatments. Additionally, the invention contemplates retaining device designs that meet the general requirements of the novel artificial occlusion kit but vary from the specific variations just described.

In one aspect of the invention, for example, the artificial occlusion kit embodiments and variations have been described specifically as applied to aneurysms in vessel walls. However, other occlusion sites adjacent to and in fluid communication with body lumens may present similar concerns as to migration of occlusion devices from an occlusion site and into an adjacent lumen. For instance, a vessel that branches off of a feeding vessel may be a body space to be occluded and the feeding vessel at a region adjacent to the branching vessel may be a desired retaining site. The present invention contemplates use of the apparatus embodiments described in such body spaces and lumens in addition to aneurysm sites in vessels.

The invention also broadly contemplates a retaining device structure that is expandable at a retaining site of a body lumen to form a barrier against migration of at least one occlusion device through an entrance zone between an occlusion site and an adjacent lumen, and that also provides a lumen for flow through the body lumen at the retaining site. Examples have been provided in the form of shape memory coils delivered through radially confining delivery sheaths or over delivery wires, in addition to an alternative balloon expandable retaining device embodiment. Various specific retaining device designs that meet the broad requirements provided, beyond the particular variations provided, are within the scope of this invention.

Also, while various retaining device designs may meet the requirements of the novel artificial occlusion kit described, at least one novel electrolytically detachable implantable medical device has been conceived of for use as a retaining device in the artificial occlusion kit. This novel implantable medical device may have useful medical applications in addition to retaining artificial occlusion devices. The scope of this aspect of the invention, while intimately pertaining to an artificial occlusion kit, should not be limited to the kit embodiments described for artificial occlusion.

Modification of the above-described variations for carrying out the invention that would be apparent to those of skill in the fields of medical device design are intended to be within the scope of the following claims.

We claim as our invention:

1. An artificial occlusion kit for implanting and retaining an artificial occlusion device in a body space to be occluded adjacent to and extending from a body lumen in a mammal, comprising:

at least one occlusion device adapted for filling at least a portion of the body space; and

a retaining device assembly having a retaining device adapted to be delivered and implanted at a retaining site in the body lumen adjacent to the body space, said retaining device having two opposite ends and forming a first shape with a first outer diameter, said retaining device being expandable to a second shape having a second outer diameter larger than said first outer diameter and sufficient to engage a body lumen wall at the retaining site such that a barrier is formed against migration of said at least one occlusion device out of the body space and into the body lumen, said second shape also forming a lumen along a longitudinal axis sufficient to allow flow of body fluids therethrough.

2. The artificial occlusion kit of claim **1**, wherein said retaining device forms said first shape when radially constrained for percutaneous delivery to the retaining site, and forms said second shape upon release from said radial constraint at the retaining site.

3. The artificial occlusion kit of claim **2**, further comprising

a delivery catheter having a proximal delivery catheter end with a proximal delivery port, an opposite distal delivery catheter end portion with a distal delivery port,

and a delivery lumen extending between said delivery ports and having a delivery lumen inner diameter less than said second outer diameter,

wherein said retaining device is slideably disposable under radial constraint within said delivery lumen.

4. The artificial occlusion kit of claim **3**, wherein said retaining device assembly further comprises a pusher that is coaxially slidable within said delivery lumen and has a distal pusher end portion and a proximal pusher end portion,

wherein said distal pusher end portion may be advanced through said delivery lumen in confronting engagement with a proximal end of said retaining device such that said retaining device may be pushed with the pusher out of the delivery lumen through the distal delivery port and into the body space.

5. The artificial occlusion kit of claim **2**, wherein said retaining device assembly further comprises a pusher having a distal pusher end portion that is detachably secured to said retaining device and a proximal pusher end portion that is adapted to be axially manipulated by a user.

6. The artificial occlusion kit of claim **5**, wherein said distal pusher end portion is electrolytically detachable from said retaining device via an electrolytically severable link.

7. The artificial occlusion kit of claim **6**, further comprising:

a power source electrically coupled to said electrolytically severable link; and

an electrode electrically coupled to said power source;

wherein a circuit is formed when said electrode and electrolytically severable joint are both in contact with a patient.

8. The artificial occlusion kit of claim **5**, wherein said distal pusher end portion is mechanically detachable from said retaining device.

9. The artificial occlusion kit of claim **2**, wherein said retaining device form said first shape when radially constrained for a percutaneous delivery to a core wire extending between said retaining device's opposite ends and constrained to said core wire by electrolytic links, and wherein said retaining device forms said second shape upon electrolytic release from said radial constraint.

10. The artificial occlusion kit of claim **9** wherein said retaining device assembly and said core wire are insulated from any fluid found in said body space and body lumen.

11. The artificial occlusion kit of claim **3**, wherein said retaining device comprises at least one wire wound into a primary helix and having a secondary shape imparted thereto.

12. The artificial occlusion kit of claim **11**, wherein said primary helix forms a primary helix lumen, said retaining device further comprising an elongate core member coaxially disposed within said primary helix lumen.

13. The artificial occlusion kit of claim **12**, wherein said elongate core member is a metal.

14. The artificial occlusion kit of claim **1**, wherein said second shape defines at least one semi-penetrable space between the body space to be occluded and the adjacent body lumen.

15. The artificial occlusion kit of claim **14**, wherein said at least one occlusion device forms a first occlusion device shape that is advanceable through said semi-penetrable space, and is also expandable to a second occlusion device shape that is not advanceable through said semi-penetrable space.

16. The artificial occlusion kit of claim **14**, wherein said second shape comprises a helix and said semi-penetrable space is the spacing between adjacent helical windings of said helix.

17. The artificial occlusion kit of claim **14**, wherein said semi-penetrable space is distensible.

18. The artificial occlusion kit of claim **17**, further comprising:

a delivery catheter having a proximal delivery catheter end with a proximal delivery port, an opposite distal delivery catheter end portion with a distal delivery port, and a delivery lumen extending between said delivery ports,

said distal delivery catheter end portion further having a tapered tip portion with a distal tip diameter smaller than said semi-penetrable space,

wherein said semi-penetrable spacing is distensible by advancing said tapered tip portion at least partially therethrough, and wherein said at least one occlusion device is advanceable within said delivery lumen.

19. The artificial occlusion kit of claim **17**, wherein said at least one occlusion device comprises two opposite ends and forms an occlusion device lumen extending between two opposite occlusion device ports at said opposite ends, said kit further comprising:

an introducer wire being coaxially advanceable through said occlusion device lumen and through said opposite occlusion device ports, and having an introducer wire tip portion that is advanceable through and is adapted to distend said semi-penetrable spacing,

wherein said at least one occlusion device is advanceable through said semi-penetrable spacing when said introducer wire tip portion is advanced through and distending said semi-penetrable spacing, and wherein said at least one occlusion device is prevented from migrating from a body space to be occluded and through said semi-penetrable spacing when said semi-penetrable spacing is not distended.

20. The artificial occlusion kit of claim **1** wherein said at least one occlusion device approximates the shape of the body space into which it is placed.

21. The artificial occlusion kit of claim **1** wherein said retaining device assembly further comprises a distal end having a distal diameter smaller than said body lumen and said second outer diameter.

* * * * *

US006171326B1

(12) **United States Patent**
Ferrera et al.

(10) **Patent No.: US 6,171,326 B1**
(45) **Date of Patent: Jan. 9, 2001**

(54) **THREE DIMENSIONAL, LOW FRICTION VASOOCCLUSIVE COIL, AND METHOD OF MANUFACTURE**

(75) Inventors: **David A. Ferrera**, San Francisco; **Daniel R. Kurz**, Sunnyvale; **Peter Wilson**, Foster City; **Crystal K. Sein-Lwyn**, Hayward; **Lok A. Lei**, San Jose, all of CA (US)

(73) Assignee: **Micrus Corporation**, Mountain View, CA (US)

(*) Notice: Under 35 U.S.C. 154(b), the term of this patent shall be extended for 0 days.

(21) Appl. No.: **09/140,495**

(22) Filed: **Aug. 27, 1998**

(51) **Int. Cl.**[7] **A61M 29/00**
(52) **U.S. Cl.** **606/191**
(58) **Field of Search** 606/191, 200, 606/70, 194, 106; 604/104

(56) **References Cited**

U.S. PATENT DOCUMENTS

1,341,052	5/1920	Gale .
1,667,730	5/1928	Green .

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

4102550 A1	8/1991	(DE) .
0 183372 A1	6/1986	(EP) .

(List continued on next page.)

OTHER PUBLICATIONS

"*Shape Memory Alloys*" by Jeff Perkins, pp. 1095–1096.
International Search Report dated Dec. 9, 1999.
Christos A. Athanasoulis, M.D. The New England Journal of Medicine, May 15, 1980 "Therapeutic Applications of Angiography" pp. 1117–1125 (1 of 2).
Christos A. Athanasoulis, M.D. The New England Journal of Medicine, May 22, 1980 "Therapeutic Applications of Angiography" pp. 1174–1179 (2 of 2).
Alex Berenstein, M.D. and Irvin I. Kricheff, M.D. "Catheter and Material Selection for Transarterial Embolization: Technical Considerations" Radiology, Sep. 1979; pp. 631–639.
O.A. Battista, et al. Journal of Applied Polymer Science 1967 "Colloidal Macromolecular Phenomena. Part II. Novel Microcrystals of Polymers" pp. 481–498.

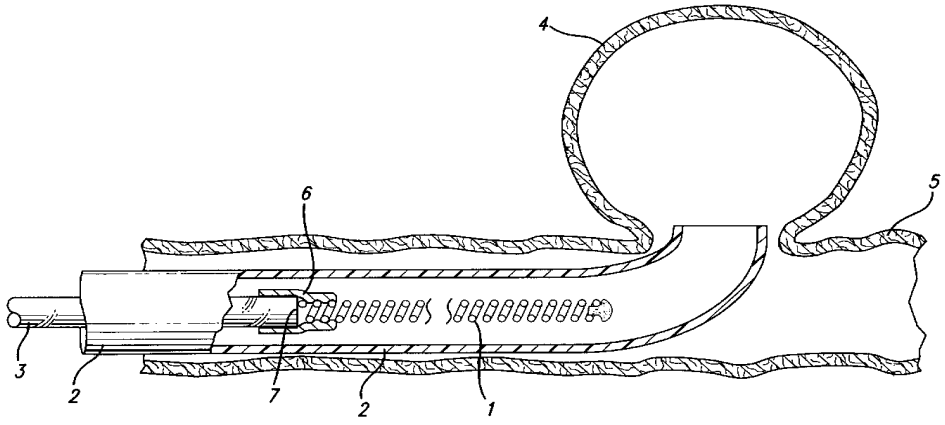
(List continued on next page.)

Primary Examiner—Michael Buiz
Assistant Examiner—(Jackie) Tan-Uyen T. Ho
(74) *Attorney, Agent, or Firm*—Fulwider Patton Lee & Utecht, LLP

(57) **ABSTRACT**

The three dimensional, low friction vasoocclusive coil has a distal portion that is three dimensionally shaped, and a proximal portion that is linear or helically shaped. The distal three dimensional portion will form a basket for filling the anatomical cavity at the site in the vasculature to be treated, while the proximal portion will fill and reinforce the basket. The vasoocclusive device is formed from at least one strand of a flexible material formed to have an a first inoperable, substantially linear configuration for insertion into and through a catheter or cannula to a desired portion of the vasculature to be treated, and a second operable, three dimensional configuration for occluding the desired portion of the vasculature to be treated. The vasoocclusive device has a distal portion having a second operable, three dimensional shape for filing the anatomical cavity at the site in the vasculature to be treated, and a proximal portion having a second operable, substantially linear shape for filling and reinforcing the distal, three dimensional shaped portion when it is implanted at the site in the vasculature to be treated. Mandrels are provided for use in the method of making the vasoocclusive device.

49 Claims, 9 Drawing Sheets



U.S. PATENT DOCUMENTS

2,078,182		4/1937	MacFarland .	
2,549,335		4/1951	Rahthus .	
3,334,629		8/1967	Cohn .	
3,649,224		3/1972	Anderson et al. .	
3,868,956		3/1975	Alfidi et al. .	
4,494,531		1/1985	Gianturco .	
4,512,338	*	4/1985	Balko et al.	606/191
4,531,933		7/1985	Norton et al. .	
4,638,803		1/1987	Rand .	
4,655,771		4/1987	Wallsten .	
4,718,907		1/1988	Karwoski et al. .	
4,748,986		6/1988	Morrison et al. .	
4,768,507		9/1988	Fischell et al. .	
4,795,458		1/1989	Regan .	
4,800,882		1/1989	Gianturco .	
4,813,925		3/1989	Anderson, Jr. et al. .	
4,820,298		4/1989	Leveen et al. .	
4,830,003		5/1989	Wolff et al. .	
4,832,055		5/1989	Palestrant .	
4,850,960		7/1989	Grayzel .	
4,856,516		8/1989	Hillstead .	
4,954,126		9/1990	Wallsten .	
4,957,479		9/1990	Roemer .	
4,957,501		9/1990	Lahille et al. .	
4,990,155		2/1991	Wilkoff .	
4,994,069	*	2/1991	Ritchart et al.	606/191
5,026,377		6/1991	Burton et al. .	
5,041,084		8/1991	DeVries et al. .	
5,064,435		11/1991	Porter .	
5,071,407		12/1991	Termin et al. .	
5,104,404		4/1992	Wolff .	
5,108,407		4/1992	Geremia et al. .	
5,122,136		6/1992	Guglielmi et al. .	
5,133,731		7/1992	Butler et al. .	
5,133,732		7/1992	Wiktor .	
5,141,502		8/1992	Macaluso, Jr. .	
5,147,370		9/1992	McNamara et al. .	
5,151,105		9/1992	Kwan-Gett .	
5,160,341		11/1992	Brenneman et al. .	
5,176,625		1/1993	Brisson .	
5,176,661		1/1993	Evard et al. .	
5,183,085		2/1993	Timmermans .	
5,186,992		2/1993	Kite, III .	
5,203,772		4/1993	Hammerslag et al. .	
5,217,484		6/1993	Marks .	
5,222,969		6/1993	Gillis .	
5,226,911		7/1993	Chee et al. .	
5,228,453		7/1993	Sepetka .	
5,234,456		8/1993	Silvestrini .	
5,250,071		10/1993	Palermo .	
5,261,916		11/1993	Engelson .	
5,304,194		4/1994	Chee et al. .	
5,304,195		4/1994	Twyford, Jr. et al. .	
5,312,415		5/1994	Palermo .	
5,314,472		5/1994	Fontaine .	
5,334,210		8/1994	Gianturco .	
5,336,205		8/1994	Zenzen et al. .	
5,342,387		8/1994	Summers .	
5,350,397		9/1994	Palermo et al. .	
5,354,295		10/1994	Guglielmi et al. .	
5,370,683		12/1994	Fontaine .	
5,382,259		1/1995	Phelps et al. .	
5,423,829		6/1995	Pham et al. .	
5,441,516		8/1995	Wang et al. .	
5,443,478		8/1995	Purdy .	
5,514,176		5/1996	Bosley, Jr. .	
5,522,822		6/1996	Phelps et al. .	
5,522,836		6/1996	Palermo .	
5,527,354		6/1996	Fontaine et al. .	
5,536,274		7/1996	Neuss .	
5,549,624		8/1996	Mirigian et al. .	
5,562,641		10/1996	Flomenblit et al. .	
5,562,698		10/1996	Parker .	
5,569,245		10/1996	Guglielmi et al. .	
5,582,619		12/1996	Ken .	
5,607,445		3/1997	Summers .	
5,624,449		4/1997	Pham et al. .	
5,624,461		4/1997	Mariant .	
5,637,113		6/1997	Tartaglia et al. .	
5,639,277		6/1997	Mariant et al. .	
5,643,254		7/1997	Scheldrup et al. .	
5,645,082		7/1997	Sung et al. .	
5,645,558		7/1997	Horton .	
5,649,949		7/1997	Wallace et al. .	
5,667,522		9/1997	Flomenblit et al. .	
5,669,931		9/1997	Kupiecki et al. .	
5,676,697		10/1997	McDonald .	
5,685,322		11/1997	Sung et al. .	
5,690,643		11/1997	Wijay .	
5,690,666		11/1997	Berenstein et al. .	
5,690,671		11/1997	McGurk et al. .	
5,700,258		12/1997	Mirigian et al. .	
5,707,389	*	1/1998	Louw et al.	606/170
5,718,711		2/1998	Berenstein et al. .	
5,725,546		3/1998	Samson .	
5,725,552		3/1998	Kotula et al. .	
5,733,329		3/1998	Wallace et al. .	
5,749,891		5/1998	Ken et al. .	
5,749,894	*	5/1998	Engelson et al.	606/191
5,766,160		6/1998	Samson et al. .	
5,843,118	*	12/1998	Sepetka et al.	606/194

FOREIGN PATENT DOCUMENTS

0 382014 A1	8/1990	(EP) .
0 747 013 A1	12/1996	(EP) .
0 747 014 A1	12/1996	(EP) .
0 743 047 A3	3/1997	(EP) .
0 765 636 A2	4/1997	(EP) .
0 820 726 A2	1/1998	(EP) .
592.182	7/1925	(FR) .
2 066 839	7/1981	(GB) .
WO 92/14408	9/1992	(WO) .
WO 94/09705	5/1994	(WO) .
WO 97/31672	9/1997	(WO) .
WO 97/48351	12/1997	(WO) .
WO 98/09570	3/1998	(WO) .
WO 99/29260	6/1999	(WO) .

OTHER PUBLICATIONS

Sadek K. Hilal, M.D. et al. Journal of Neurological Surgery "Therapeutic Percutaneous Embolization for Extra–Axial Vascular Lesions of the Head, Neck and Spine" Sep., 1975; pp. 275–287.

Stephen L. Kaufman, M.D. et al. Investigative Radiology, May–Jun. 1978 "Transcatheter Embolization with Microfibrillar Collagen in Swine"; pp. 200–204.

Ashok J. Kumar, et al., Journal of Neuroradiology (1982) "Preoperative Embolization of Hypervascular Head and Neck Neoplasms Using Microfibrillar Collagen", pp. 163–168.

Richard E. Latchaw, M.D. et al., Radiology (1979) "Polyvinyl Foam Embolization of Vascular and Neoplastic Lesions of the Head, Neck and Spine" pp. 669–679.

Stewart R. Reuter, M.D. et al. American Journal of Radiology, Sep. 1975 "Selective Arterial Embolization for Control of Massive Upper Gastrointestinal Bleeding" pp. 119–126.
Glenn H. Roberson, et al., American Journal of Radiology, Oct. 1979 "Therapeutic Embolization of Juvenile Angiofibroma" pp. 657–663.
Sidney Wallace, M.D. et al., Cancer, Oct. 1979 "Arterial Occlusion of Pelvic Bone Tumors"; pp. 322–325 & 661–663.
"Mechanical Devices for Arterial Occlusion" By C. Gianturco, M.D., et al., Jul. 1975 pp. 428–435.
"Therapeutic Vascular Occlusion Utilizing Steel Coil Technique: Clinical Applications" By Sidney Wallace, et al., Am J. Roentgenol (1976); pp. 381–387.
"Transcatheter Intravascular Coil Occlusion of Experimental Arteriovenous Fistulas", By James H. Anderson, et al., Am. J. Roentgenol, Nov. 1977, pp.795–798.
" 'Mini' Gianturco Stainless Steel Coils for Transcatheter Vascular Occlusion" By James H. Anderson, et al., From the Department of Diagnostic Radiology at the University of Texas System Cancer Center , Aug. 1978, pp. 301–303.
"A New Improved Coil for Tapered–Tip Catheter for Arterial Occlusion" By Vincent P. Chuang, M.D., et al., May 1980, pp. 507–509.

* cited by examiner

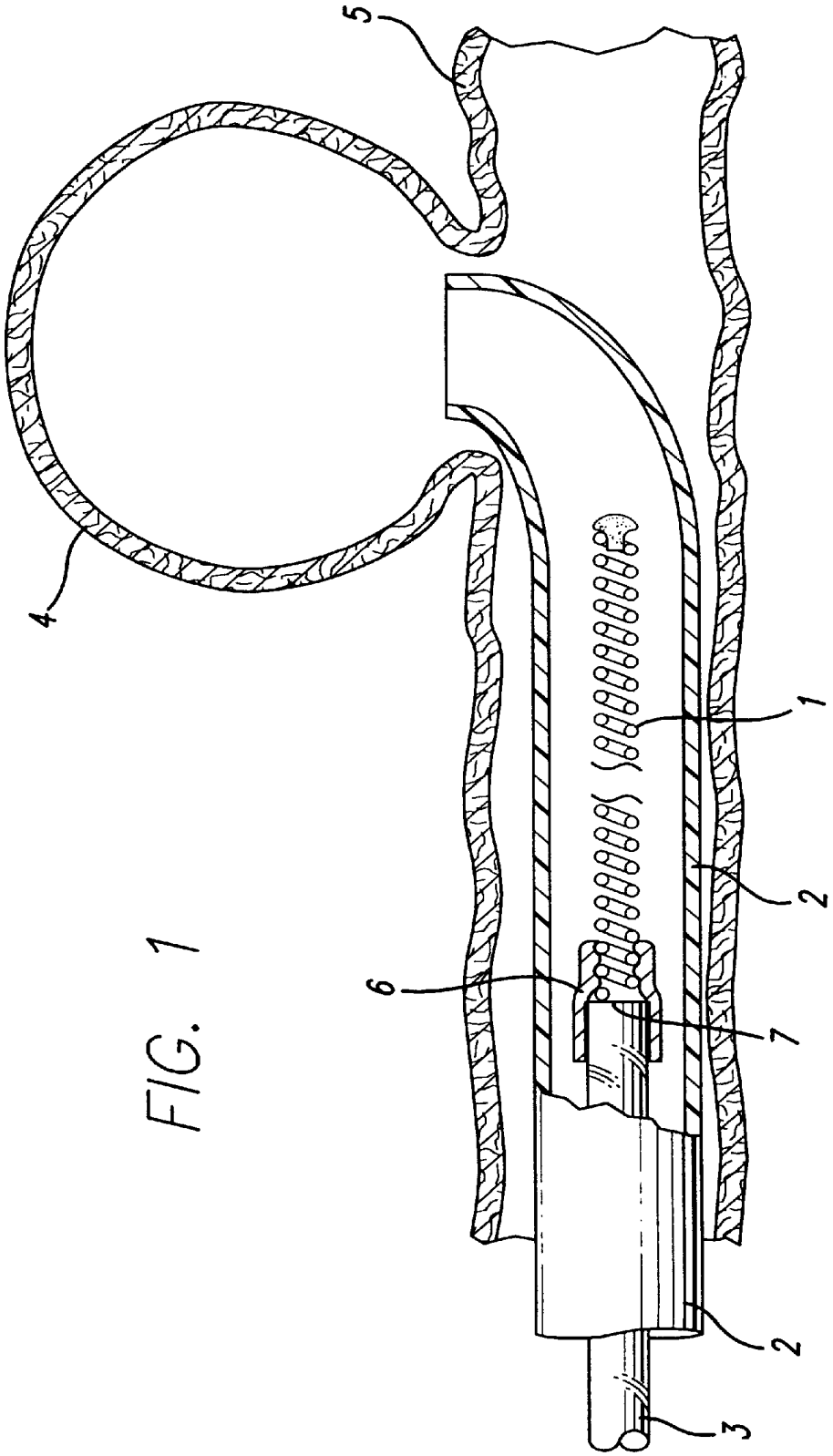


FIG. 1

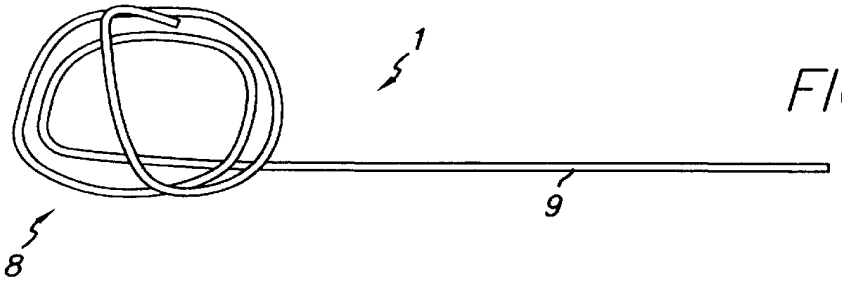


FIG. 2

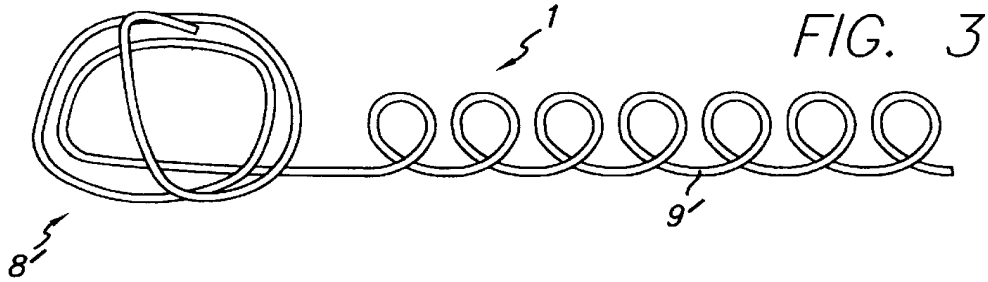


FIG. 3

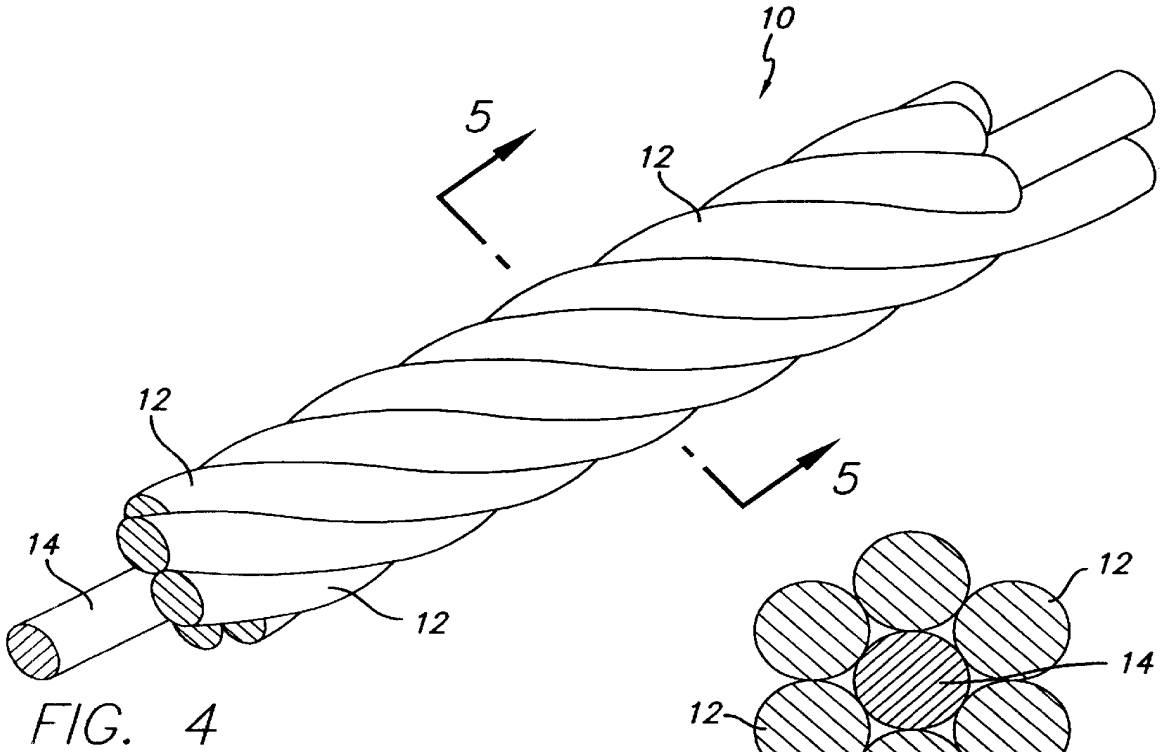


FIG. 4

FIG. 5

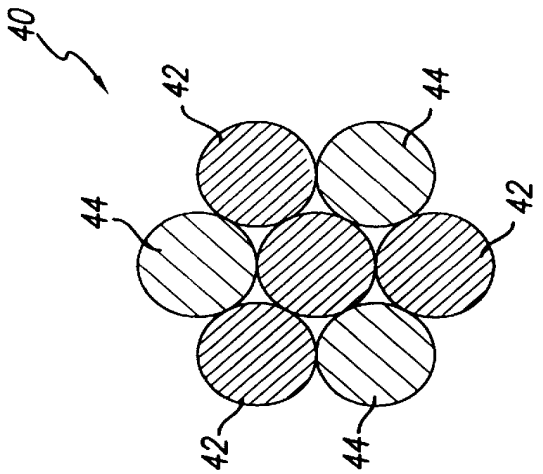


FIG. 6

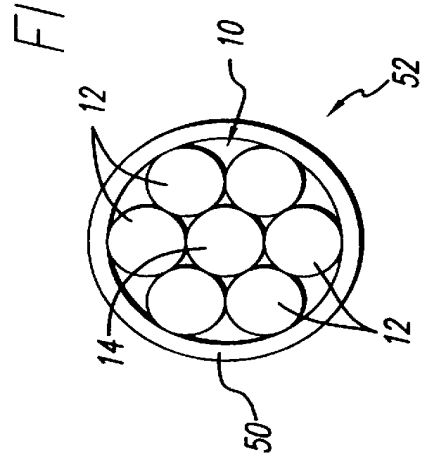


FIG. 7

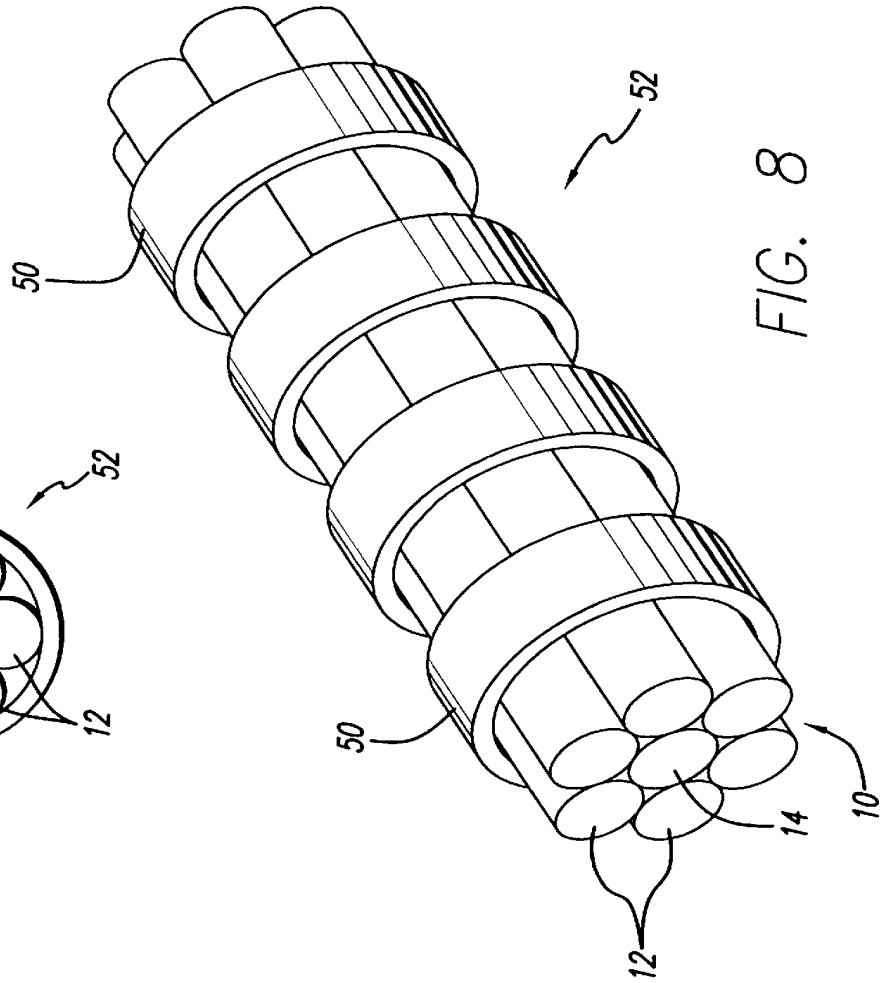


FIG. 8

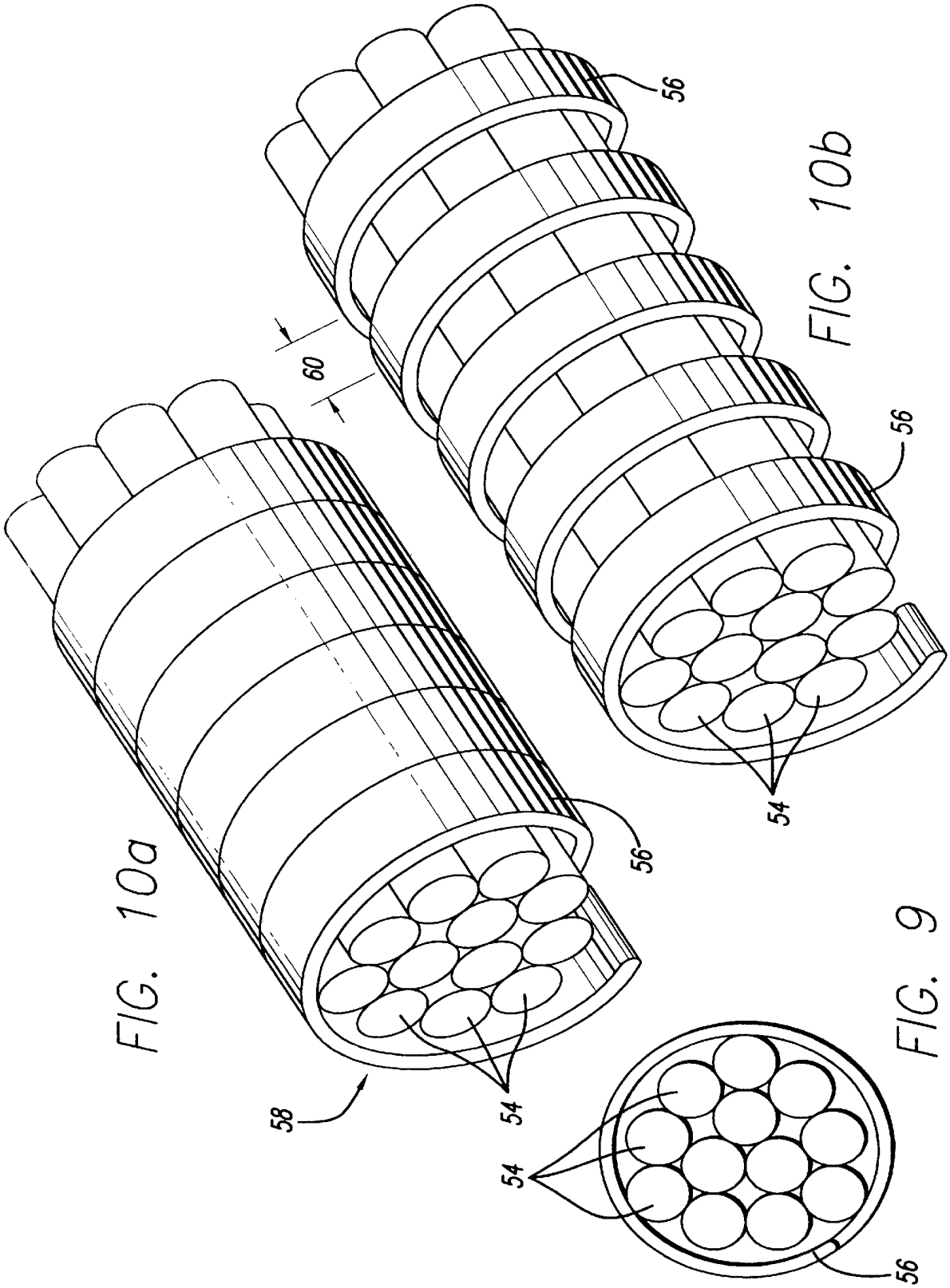


FIG. 10a

FIG. 10b

FIG. 9

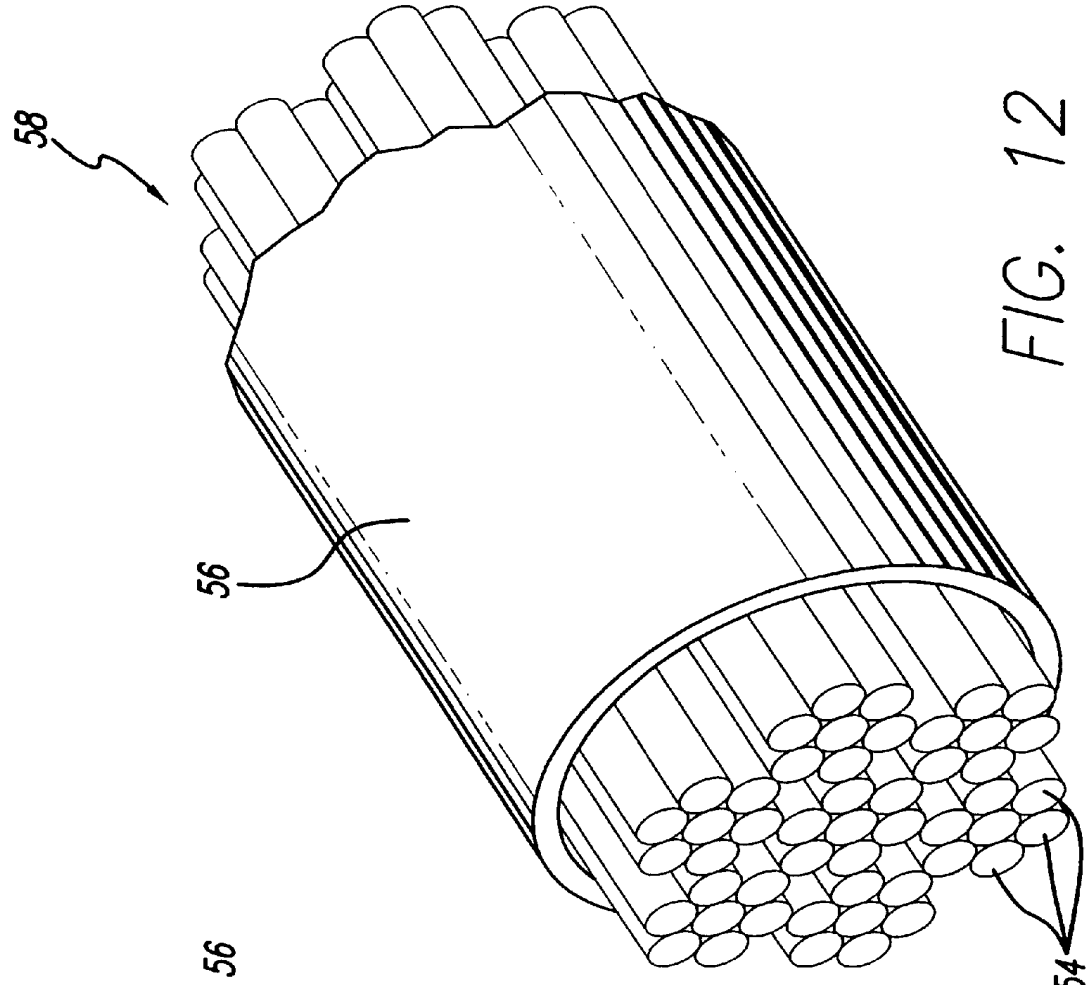


FIG. 12

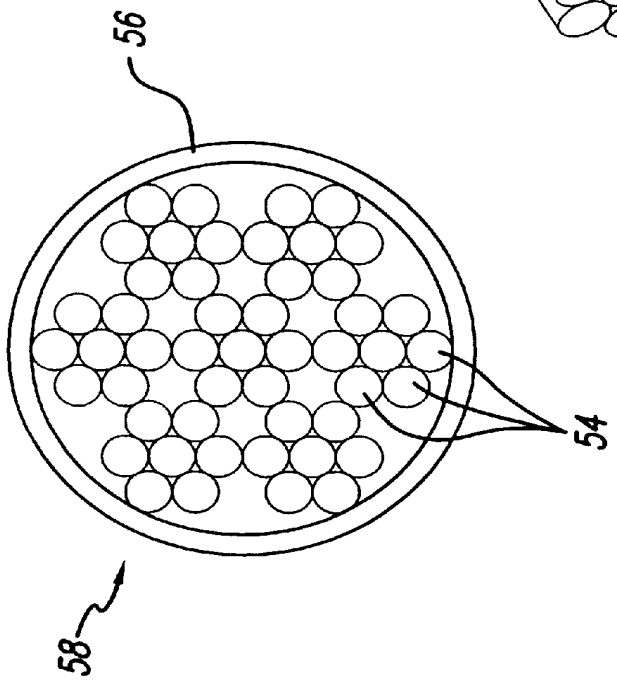


FIG. 11

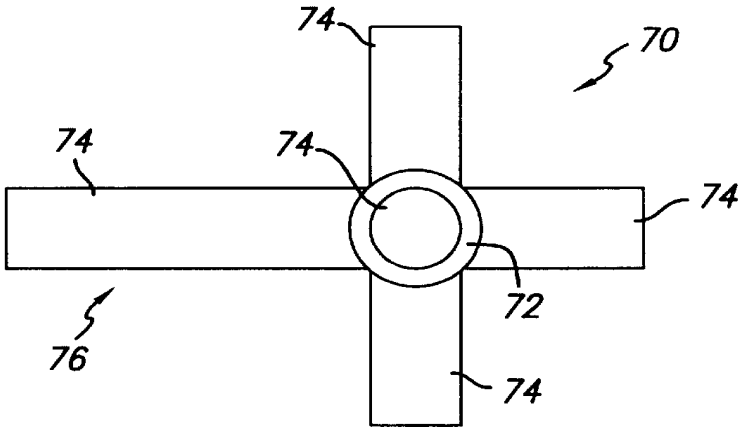


FIG. 13A

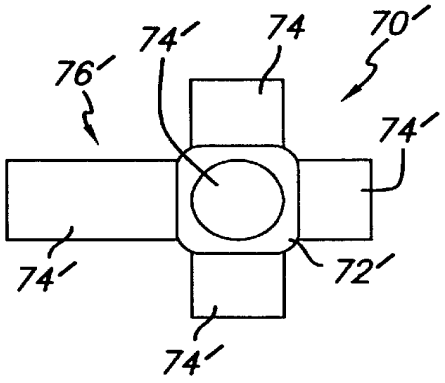


FIG. 14

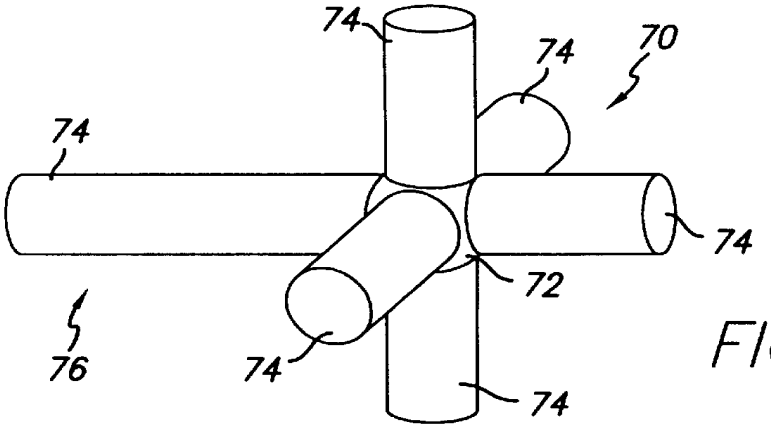


FIG. 13B

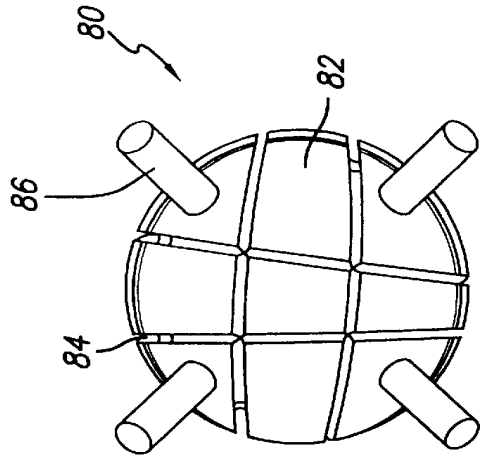


FIG. 15C

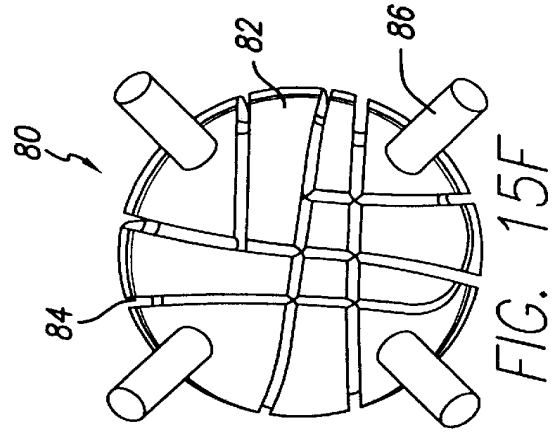


FIG. 15F

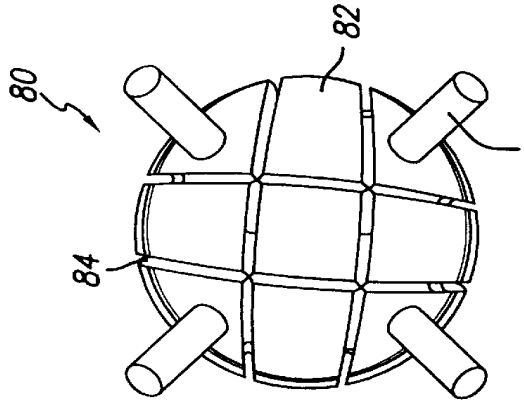


FIG. 15B

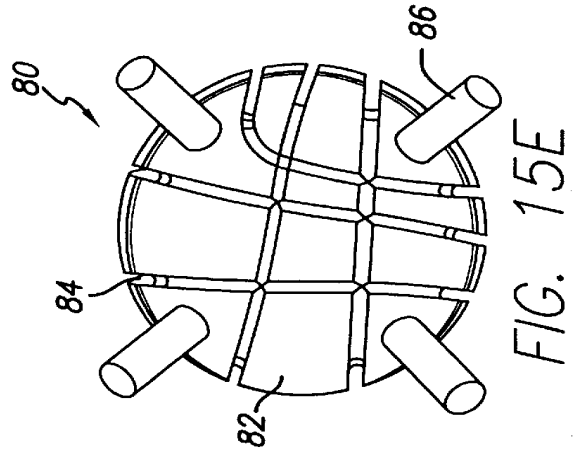


FIG. 15E

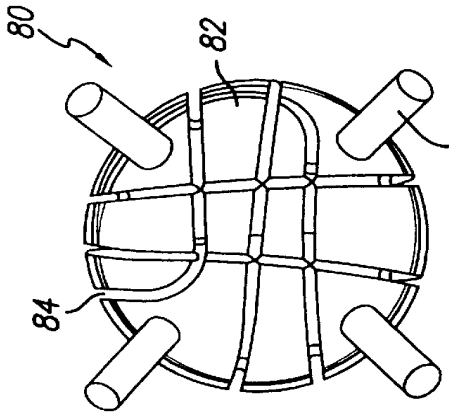


FIG. 15A

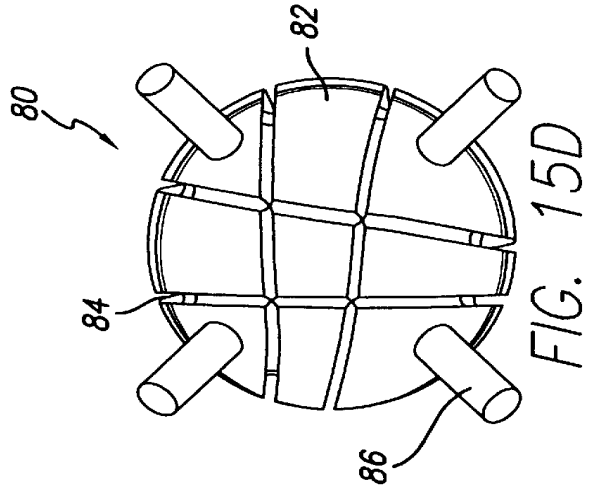


FIG. 15D

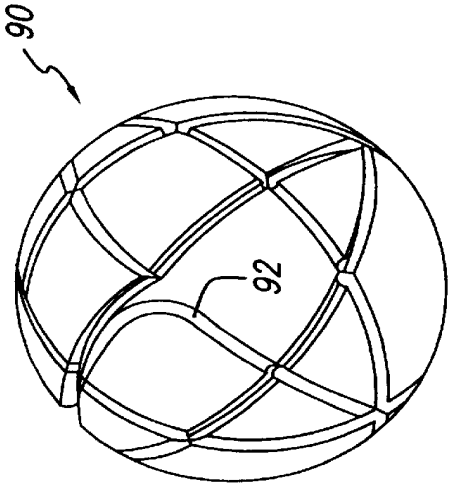


FIG. 16B

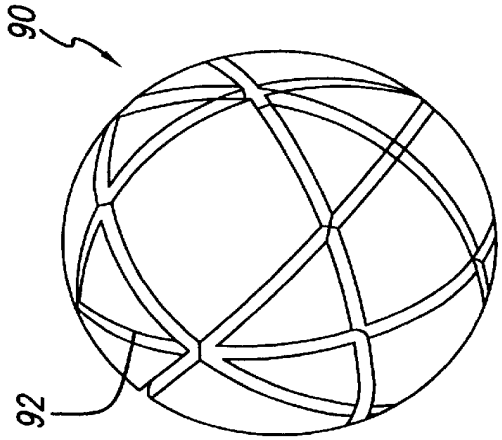


FIG. 16E

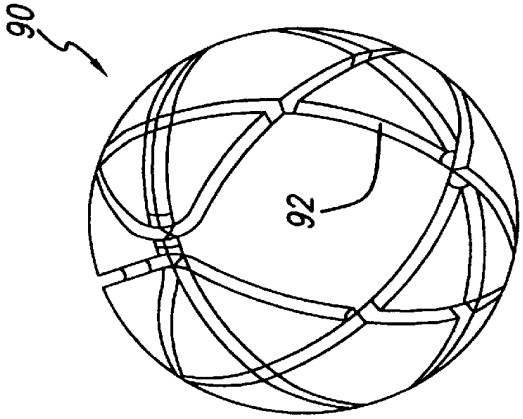


FIG. 16C

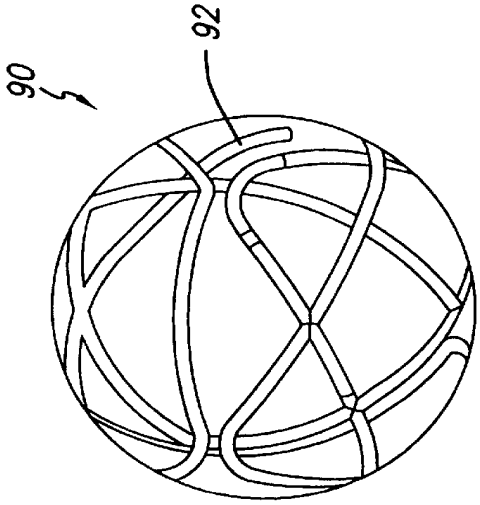


FIG. 16A

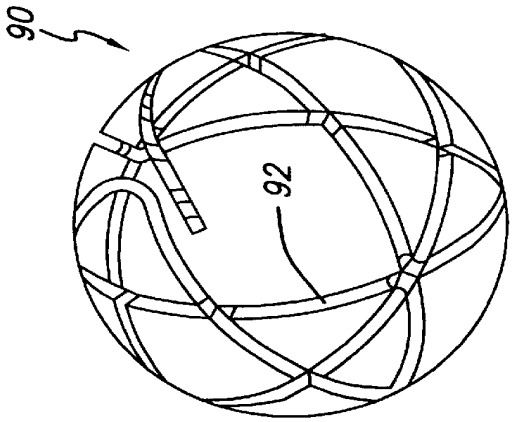


FIG. 16D

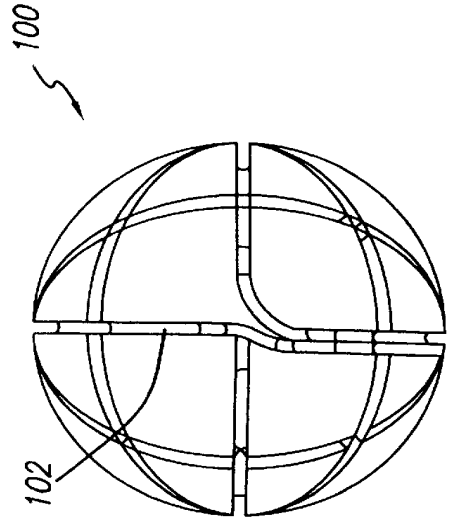


FIG. 17B

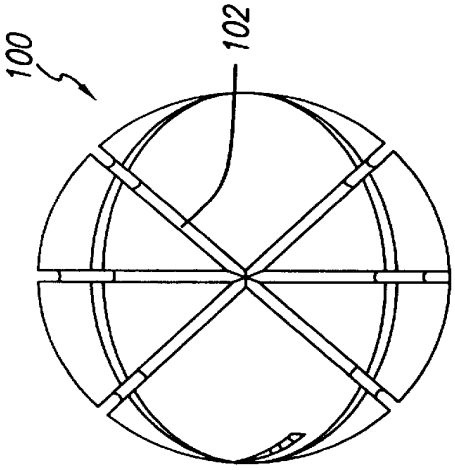


FIG. 17A

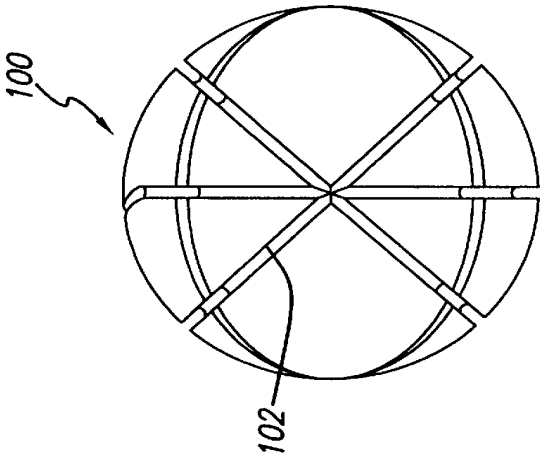


FIG. 17E

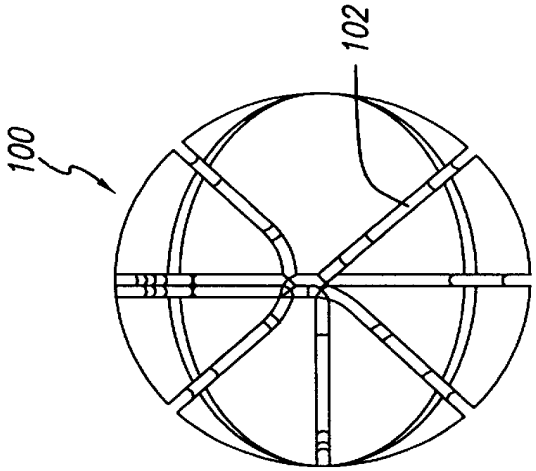


FIG. 17C

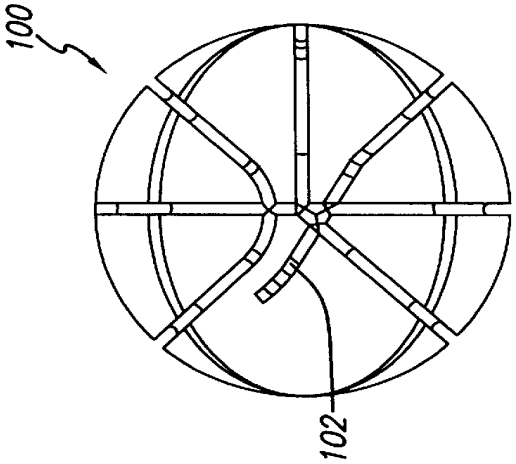


FIG. 17D

THREE DIMENSIONAL, LOW FRICTION VASOOCCLUSIVE COIL, AND METHOD OF MANUFACTURE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to vasoocclusive devices, and more particularly concerns a vasoocclusive device that has a first elongated, reduced friction configuration in which the vasoocclusive device may be deployed through a catheter or cannula to an anatomical cavity at a site in the vasculature to be treated, and that has a three dimensional second configuration assumed by the vasoocclusive device at the site to be treated for filling the anatomical cavity.

2. Description of Related Art

The art and science of interventional therapy and surgery has continually progressed towards treatment of internal defects and diseases by use of ever smaller incisions or access through the vasculature or body openings in order to reduce the trauma to tissue surrounding the treatment site. One important aspect of such treatments involves the use of catheters to place therapeutic devices at a treatment site by access through the vasculature. Examples of such procedures include transluminal angioplasty, placement of stents to reinforce the walls of a blood vessel or the like and the use of vasoocclusive devices to treat defects in the vasculature. There is a constant drive by those practicing in the art to develop new and more capable systems for such applications. When coupled with developments in biological treatment capabilities, there is an expanding need for technologies that enhance the performance of interventional therapeutic devices and systems.

One specific field of interventional therapy that has been able to advantageously use recent developments in technology is the treatment of neurovascular defects. More specifically, as smaller and more capable structures and materials have been developed, treatment of vascular defects in the human brain which were previously untreatable or represented unacceptable risks via conventional surgery have become amenable to treatment. One type of non-surgical therapy that has become advantageous for the treatment of defects in the neurovasculature has been the placement by way of a catheter of vasoocclusive devices in a damaged portion of a vein or artery.

Vasoocclusion devices are therapeutic devices that are placed within the vasculature of the human body, typically via a catheter, either to block the flow of blood through a vessel making up that portion of the vasculature through the formation of an embolus or to form such an embolus within an aneurysm stemming from the vessel. The vasoocclusive devices can take a variety of configurations, and are generally formed of one or more elements that are larger in the deployed configuration than when they are within the delivery catheter prior to placement. One widely used vasoocclusive device is a helical wire coil having a deployed configuration which may be dimensioned to engage the walls of the vessels. One anatomically shaped vasoocclusive device that forms itself into a shape of an anatomical cavity such as an aneurysm and is made of a pre-formed strand of flexible material that can be a nickel titanium alloy is known from U.S. Pat. No. 5,645,558, which is specifically incorporated by reference herein. That vasoocclusive device comprises one or more vasoocclusive members wound to form a generally spherical or ovoid shape in a relaxed state. The vasoocclusive members can be a helically wound coil or a co-woven braid formed of a biocompatible material, and

the device is sized and shaped to fit within a vascular cavity or vesicle, such as for treatment of an aneurysm or fistula. The vasoocclusive member can be first helically wound or braided in a generally linear fashion, and is then wound around an appropriately shaped mandrel or form, and heat treated to retain the shape after removal from the heating form. Radiopacity can be provided in the vasoocclusive members by weaving in synthetic or natural fibers filled with powdered radiopaque material, such as powdered tantalum, powdered tungsten, powdered bismuth oxide or powdered barium sulfate, which can potentially be released during vascular surgery.

The delivery of such vasoocclusive devices can be accomplished by a variety of means, including via a catheter in which the device is pushed through the catheter by a pusher to deploy the device. The vasoocclusive devices, which can have a primary shape of a coil of wire that is then formed into a more complex secondary shape, can be produced in such a way that they will pass through the lumen of a catheter in a linear shape and take on a complex shape as originally formed after being deployed into the area of interest, such as an aneurysm. A variety of detachment mechanisms to release the device from a pusher have been developed and are known in the art.

For treatment of areas of the small diameter vasculature such as a small artery or vein in the brain, for example, and for treatment of aneurysms and the like, micro-coils formed of very small diameter wire are used in order to restrict, reinforce, or to occlude such small diameter areas of the vasculature. A variety of materials have been suggested for use in such micro-coils, including nickel-titanium alloys, copper, stainless steel, platinum, tungsten, various plastics or the like, each of which offers certain benefits in various applications. Nickel-titanium alloys are particularly advantageous for the fabrication of such micro coils, in that they can have super-elastic or shape memory properties, and thus can be manufactured to easily fit into a linear portion of a catheter, but attain their originally formed, more complex shape when deployed.

One conventional vasoocclusive coil is known, for example, that has a three dimensional in-filling coil configuration, formed by winding a wire into a helix, and then winding the helix into a secondary form which forms a generally spherical shape, by winding the primary coil about poles placed on winding mandrel. The secondary wound coil is then annealed on the winding mandrel, and the coil is then removed from the winding mandrel and loaded into a carrier for introduction into a delivery catheter. Another similar type of vasoocclusive device is known that can be formed from one or more strands, and can be wound to form a generally spherical or ovoid shape when released and relaxed at the site to be treated. Another implantable vasoocclusive device having multiple secondary layers of primary windings has a final shape that is a generally spherical coil formed of linear or helical primary coils that are wound into a secondary form having three layers. The inner winding is wound and then the second layer formed by winding in the opposite direction of the first layer. The final configuration is a chunky or stepped shape approximately a sphere, ovoid, or egg. Yet another conventional implant for vessel occlusion is made from helical elements of metal or synthetic material by twisting or coiling the elements and forming them into a secondary shape such as a rosette or double rosette for implantation using a catheter, and another vasoocclusive device is known that has a final conical shape. However, due to the tendency of such three dimensional shaped coils to transform into their expanded, final forms

when introduced into a catheter in the body, they are inherently more difficult than a helical coil or a straight wire or micro-cable to push through such a catheter for delivery to a site in the vasculature to be treated, due to friction between the coil and the catheter through which it is delivered to the site to be treated, which can even result in misalignment of the coil within the catheter during delivery.

There thus remains a need for a vasoocclusive device that has a three dimensional final form that can be used to fill an anatomical cavity at a site in the vasculature to be treated, reduces friction between the coil and the catheter through which it is delivered to the site to be treated, and ultimately helps to prevent coil misalignment. The present invention meets these and other needs.

SUMMARY OF THE INVENTION

Briefly, and in general terms, the present invention provides for an improved vasoocclusive coil, and a method of making the coil, that has a distal portion that is three dimensionally shaped, and a proximal portion that is linear or helically shaped, in order to combine the best qualities of a three dimensional coil and a linear or helical coil. The distal three dimensional portion will form a basket for filling the anatomical cavity at the site in the vasculature to be treated, while the proximal portion will fill and reinforce the basket. This combination will reduce friction within a catheter or cannula being used to deliver the vasoocclusive coil to the site in the vasculature to be treated, and ultimately helps prevent coil realignment or misalignment. The ultimate coil volume that otherwise might be limited due to frictional constraints of three dimensional coils will not be compromised with the device of the present invention.

The present invention accordingly provides for a vasoocclusive device that is adapted to be inserted into a portion of a vasculature for occluding the portion of the vasculature for use in interventional therapy and vascular surgery. The vasoocclusive device comprises at least one strand of a flexible material formed to have an a first inoperable, substantially linear configuration for insertion into and through a catheter or cannula to a desired portion of the vasculature to be treated, and a second operable, three dimensional configuration for occluding the desired portion of the vasculature to be treated. The vasoocclusive device advantageously has a distal portion having a second operable, three dimensional shape for filling the anatomical cavity at the site in the vasculature to be treated, and a proximal portion having a second operable, substantially linear shape for filling and reinforcing the distal, three dimensional shaped portion when it is implanted at the site in the vasculature to be treated.

The present invention also provides for a method of making the vasoocclusive device. The method generally comprises the steps of winding at least one strand of a flexible shape memory material about a mandrel formed of a refractory material in a three dimensional configuration of the vasoocclusive coil to form a distal portion of the vasoocclusive coil; heating the at least one strand of a flexible shape memory material wound about the mandrel for a sufficient period of time to impart the form to the shape memory material included in the device to form an operable, three dimensional configuration of the vasoocclusive coil; removing the vasoocclusive coil from the mandrel; and cold working the vasoocclusive coil into a desired elongated configuration for placement into a catheter or cannula for use. In one presently preferred embodiment, the mandrel about which the at least one flexible strand forming the vasoocclusive coil is wound has a substantially spherical body portion having a plurality of circumferential grooves to form a three dimensional configuration of a distal portion of the vasoocclusive coil. In another presently preferred embodiment, the mandrel about which the at least one flexible strand forming the vasoocclusive coil is wound has a substantially spherical body with a plurality of posts disposed on the body. In a preferred aspect, six posts are disposed on the body aligned with the three orthogonal x, y and z axes through the body of the mandrel, for aligning and shaping the distal portion of the vasoocclusive device as it is wound on the mandrel. One of the posts is preferably made longer than the other posts, to serve as a mandrel for helically winding the proximal portion of the vasoocclusive coil. In another preferred aspect of the method, the step of heating comprises heating the at least one strand of a flexible shape memory material wound about the mandrel at a temperature of about 1100° F. for at least about 4 hours to impart the form to the shape memory material included in the device to form an operable, three dimensional configuration of the distal portion of the vasoocclusive coil.

These and other aspects and advantages of the invention will become apparent from the following detailed description and the accompanying drawings, which illustrate by way of example the features of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a cross section of a vascular member with an aneurysm illustrating the approach of a vasoocclusive coil towards the aneurysm.

FIG. **2** is a side elevational view showing a first embodiment of a second operable, three dimensional configuration of the vasoocclusive coil of the invention.

FIG. **3** is a side elevational view showing a second embodiment of a second operable, three dimensional configuration of the vasoocclusive coil of the invention.

FIG. **4** is a perspective view of a radiopaque microstrand cable used in forming the vasoocclusive coil according to the invention.

FIG. **5** is a cross-section at **5**—**5** of FIG. **4**.

FIG. **6** is an alternate preferred embodiment of the invention including a plurality of radiopaque strands within the cable.

FIG. **7** is an alternate preferred embodiment of the present invention wherein strands of the cable are arranged within an exterior binding consisting of multiple straps about the cable.

FIG. **8** is a perspective view of the embodiment of FIG. **7**.

FIG. **9** is an alternative embodiment to the embodiment of FIG. **8** wherein the external binding of the cable represents a sheath wound about the cable.

FIGS. **10***a* and **10***b* are perspectives of alternative embodiments of the embodiment of FIG. **9**.

FIG. **11** is a cross-section of an alternative embodiment in which a plurality of multi-strand cables are included within an external sheath surrounding the cable.

FIG. **12** is a perspective view of the embodiment of FIG. **11**.

FIG. **13**A is a top plan view of a first embodiment of a mandrel used for making the vasoocclusive coil according to the method of the invention.

FIG. **13**B is a perspective view of the mandrel of FIG. **13**A.

FIG. **14** is a plan view of a variant of the first embodiment of FIGS. **13**A and **13**B.

FIG. **15**A is a top plan view of a second preferred embodiment of a mandrel used for making the vasoocclusive coil according to the method of the invention.

FIG. **15**B is a front plan view of the mandrel of FIG. **15**A.

FIG. **15**C is a bottom plan view of the mandrel of FIG. **15**A.

FIG. **15**D is a left side plan view of the mandrel of FIG. **15**A.

FIG. **15**E is a right side plan view of the mandrel of FIG. **15**A.

FIG. **15**F is a rear plan view of the mandrel of FIG. **15**A.

FIG. **16**A is a front plan view of a third preferred embodiment of a mandrel used for making the vasoocclusive coil according to the method of the invention.

FIG. **16**B is a bottom plan view of the mandrel of FIG. **16**A.

FIG. **16**C is a left side plan view of the mandrel of FIG. **16**A.

FIG. **16**D is a right side plan view of the mandrel of FIG. **16**A.

FIG. **16**E is a rear plan view of the mandrel of FIG. **16**A.

FIG. **17**A is a top plan view of a fourth preferred embodiment of a mandrel used for making the vasoocclusive coil according to the method of the invention.

FIG. **17**B is a front plan view of the mandrel of FIG. **17**A.

FIG. **17**C is a bottom plan view of the mandrel of FIG. **17**A.

FIG. **17**D is a left side plan view of the mandrel of FIG. **17**A.

FIG. **17**E is a right side plan view of the mandrel of FIG. **17**A.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

While conventional three dimensional and spherical vasoocclusive coils have been developed, such three dimensional shaped coils tend to transform into their expanded, final forms when introduced into a catheter in the body, making them inherently more difficult than a simple helical coil or straight wire to push through a catheter or cannula for delivery to a site in the vasculature to be treated, due to friction between the coil and the catheter through which it is delivered to the site to be treated, and that can even result in misalignment of the coil within the catheter during delivery.

As is illustrated in the drawings, the invention is accordingly embodied in a vasoocclusive device that is adapted to be inserted into a portion of a vasculature for occluding the portion of the vasculature for use in interventional therapy and vascular surgery. The vasoocclusive coil **1** is formed from at least one strand of a flexible material formed to have a first inoperable, substantially linear configuration, as illustrated in FIG. **1**, for insertion through a micro-catheter **2** into a desired portion of the vasculature to be treated, such as an aneurysm, or other anatomical malformation of the vasculature to be treated, and a second operable, three dimensional configuration, as illustrated in FIGS. **2** and **3**, for occluding the desired portion of the vasculature to be treated.

FIG. **1** illustrates a helically wound vasoocclusive coil **1** which is formed to fit within the micro-catheter for insertion into an area upon which a therapeutic procedure is to be performed. FIG. **1** further shows a catheter pusher member **3** for delivering a vasoocclusive coil **1** for insertion into an aneurysm **4** projecting laterally from a blood vessel **5**. The end of the micro-catheter **2** is typically introduced into the opening of the aneurism by use of a guide wire (note shown), and the coil and pusher member are introduced into the micro-catheter to insert the vasoocclusive coil into the aneurysm. In a presently preferred embodiment, catheter pusher member to which the vasoocclusive coil is mounted is an optical fiber pusher which is attached to the coil by a collar **6** of shape memory material as described in co-pending application Ser. Nos. 09/019,814 and 09/072,314 the disclosure of which are incorporated herein by reference. The vasoocclusive coil is typically introduced into the aneurysm and is then pushed from the micro-catheter until the vasoocclusive coil fills the cavity.

In one presently preferred embodiment, the shape memory collar **6** is heated to a temperature which allows it to be shrunk onto the vasoocclusive coil. The collar can be attached to optical fiber pusher by an adhesive which retains high strength at temperatures beyond the shape memory material transition point. After insertion, and when an operator is satisfied that the device is properly deployed, light energy from a source of coherent light is introduced into the proximal end of the optical fiber (not shown) and propagated in the distal end **7** of the fiber to cause the shape memory material collar to return to its previous shape and release the vasoocclusive coil. Those skilled in the art will recognize that the invention can also be used with a variety of other placement catheter systems, and it is not intended that the invention be limited to the placement concepts illustrated by way of example.

Referring to FIGS. **2** and **3**, the vasoocclusive device preferably has a distal portion **8** having a second operable, three dimensional shape for filling the anatomical cavity at the site in the vasculature to be treated, and a proximal portion having a second operable, substantially linear shape for filling and reinforcing the distal, three dimensional shaped portion when the vasoocclusive device is implanted at the site in the vasculature to be treated. The distal portion preferably has a second operable, three dimensional shape that is substantially spherical. As is illustrated in FIG. **2**, in one presently preferred embodiment, the proximal portion **9** is substantially linear, and as is illustrated in FIG. **3**, in another presently preferred embodiment, the proximal portion **9'** is substantially helical.

In a presently preferred aspect of the invention, the vasoocclusive coils are formed from a multi-stranded micro-cable, although the vasoocclusive coils can also be made from a single strand of a flexible material formed to have an a first inoperable, substantially linear configuration for insertion into and through a catheter or cannula to a desired portion of the vasculature to be treated, and a second operable, three dimensional configuration for occluding the desired portion of the vasculature to be treated. As is illustrated in FIG. **4**, the vasoocclusive coils are preferably formed from a multi-stranded micro-cable **10** that is typically approximately from 0.0021 to 0.0045 inches in diameter, and comprises a plurality of flexible strands **12** of nickel-titanium alloy, with at least one centrally, axially disposed radiopaque wire **14** which is approximately from 0.0007 to 0.0015 inches in diameter. While the above stated diameters represent those presently known to be compatible with the invention, larger or smaller diameters may be useful for particular applications. The central radiopaque wire **14** can be formed of platinum or gold, for example, or other similar suitable radiopaque metals, in order to provide a

radiopaque marker of the deployed configuration of a device made of the cable during vascular surgery.

There are numerous benefits to the novel construction of the invention for use in interventional devices and the like. By using the stranded or micro-cable construction of the invention, a vasoocclusive device made from the micro-cable becomes virtually kink resistant compared to the single strand wires now commonly used in micro-coils. The multi-strand cable construction of the invention allows the micro-wires of the cable to slip across each other and reinforce each other rather than break or take a set. Also, by incorporating a stranded radiopaque material such as platinum, tungsten or gold into the cable construction, the device is radiopaque in sizes much smaller than with other constructions.

FIG. **5** is a cross-section of the micro-cable of FIG. **4** at **5**—**5** illustrating one presently preferred arrangement of the strands within the cable. In this embodiment, the exterior strands **12** are formed of a resilient material chosen to provide the characteristics desired for a specific application in interventional therapies. In a presently preferred embodiment, this material is a nickel titanium super-elastic alloy which is heat treated such that the alloy is highly flexible at a temperature appropriate for introduction into the body via a catheter or cannula. By choosing such a material for micro-coils and the like, the devices formed from the micro-cable can be relatively easily placed into the appropriate body cavity and after placement, the device will take on a shape designed to optimize the therapeutic purposes desired for the device. As illustrated in FIG. **5**, such a cable can have a central core **14** of a radiopaque material such as gold or platinum, thus dramatically enhancing the radiopacity of the cable. Even a solid super-elastic wire of the same diameter as the cable would have substantially less radiopacity than the cable of the invention with the central gold or platinum wire and the construction of the invention provides numerous other highly desirable characteristics. Among these characteristics is the relative flexibility and resistance to kinking of the cable compared to an equivalent single wire and substantially greater accommodation of the cable to bending, etc., with resultant lessening of trauma to the surrounding tissue and ease of placement in a small body cavity.

While one presently preferred implementation of the micro-cable of the invention has been illustrated, those skilled in the art will appreciate that other variations of the invention may have advantages for certain purposes. FIG. **6** is an example of one such construction **40** in which radiopacity is more desirable than in other forms and for that reason a number of radiopaque strands **42**, in this illustration four in number, are formed into the cable along with three resilient material strands **44**. It will also be appreciated that a larger or smaller number of strands may be incorporated into a given cable and the cables may be formed of multiple cables in order to provide desired bending and strength characteristics. It will also be appreciated by those skilled in the art that the invention is adaptable to the use of a variety of materials which by themselves would not have been easily adaptable to micro devices for interventional therapies. For instance, materials such as copper are useful for intrauterine devices and the like, but copper wire, even when heavily alloyed, has certain limitations for use in such devices. By use of the present invention, composite cables incorporating one or more strands of a desired material can be configured with other strands providing strength, flexibility, shape memory, super-elasticity, radiopacity or the like for previously unavailable characteristics in micro devices.

FIG. **7** illustrates a cross-section of an additional presently preferred embodiment of the invention in which the strands **12**, **14** of the micro-cable **10** are bundled and banded at intervals by bands **50** to produce a composite banded cable **52** in order to provide increased flexibility without unraveling or dislocation of the strands in the cable. FIG. **8** is a perspective view of the banded cable **50** of this embodiment. While the illustrated configuration shows the strands being laid parallel within the cable, it is also possible in this construction to include both twisted cables as the primary cables **10** within the outer bands **50** to form the composite cable **52**. This configuration can use one or more longitudinal strands **14** which are radiopaque, thus providing a continuous indication of radiopacity within the cable. As a further alternative embodiment, it is possible for the longitudinal cable **52** to be formed of a single inner cable **10** with bands **50**.

FIG. **9** illustrates a further embodiment of the invention in which longitudinal strands of cables are contained within a wound cover **56** for the purposes of providing a composite guide wire or the like **58** having improved torqueability. Such a construction has particular advantages for guidewire designs having improved radiopacity in very small diameters. It will be appreciated that in this configuration, as well as the other longitudinally arranged multi-stranded cables, the number of strands and the degree to which they extend along the cable within the sheath is a variable which can be used to provide increased stiffness, pushability and torqueability in some sections with greater flexibility in others. Additionally, composite cables according to the invention can incorporate additional elements normally not available in solid guide wires, such as optical, thermal or ultrasound imaging elements, therapeutic agent delivery catheters, and can take advantage of materials which are not readily adaptable to prior art catheter or guide wire designs incorporating a primary wire structured element. FIGS. **10***a* and **10***b* illustrate a further variable available because of the invention; the exterior wrapped cover **56** can be wound at greater or lesser intervals **60** along the outside to provide variations in the torqueability and stiffness of the composite cable. Also, the thickness and width of the wrapping cover **56**, as well as its material composition along the composite guide wire **58**, can offer further capabilities for customizing the design for various applications. These advantages can be combined with the benefits of shape memory or super-elastic alloys to create guidewires and other devices with heretofore unavailable capabilities.

FIGS. **11** and **12** illustrate a cross-section of a micro-cable according to the invention which has at least one overall exterior sheath to contain the microcable. The micro-cable may be made of one or more multiple strand elements which may further include twisted or longitudinal strands within their construction. The sheath may also be used to control the torqueability characteristics of the cable and as discussed in co-pending application, Ser. No. 08/986,004, the sheath may be multi-layered with different materials in order to provide a graduated bending and stiffness characteristic over the length of the cable.

It will be appreciated that a three dimensional occlusive device adapted to be inserted into a portion of a vasculature for occluding the portion of the vasculature for use in interventional therapy and vascular surgery, can be formed as described above, from at least one multi-stranded micro-cable having a plurality of flexible strands of a resilient material, with at least one radiopaque strand to provide a radiopaque marker for the device during vascular surgery. The occlusive device is configured to have a first inoperable,

substantially linear, elongated configuration for insertion into and through a catheter or cannula to a desired portion of the vasculature to be treated, and a second operable, three dimensional configuration for occluding the desired portion of the vasculature to be treated.

In the method of making the vasoocclusive coils of the invention, a mandrel is used for annealing the coils in the desired second operable, three dimensional shape. A mandrel suitable for making such second operable, three dimensional shaped occlusive devices can be formed of a refractory material, such as alumina or zirconia, for example. The mandrel typically has the general three dimensional shape that the occlusive device will be given, and can have a generally helical, conical, or spherical shape, or can have a unique shape designed to provide such a primary configuration to the occlusive device. The mandrel forms a support for the winding and heat treatment of the micro-cable, plurality of microcables, or composite micro-cable occlusive device as described above, and ideally will not contaminate the occlusive device during heat treatment of the device.

In one presently preferred embodiment illustrated in FIGS. **13**A and **13**B, one or more of the flexible strands forming the vasoocclusive coil are wound around the surface of a mandrel **70** having a substantially spherical main body **72** with six cylindrical posts **74** having a diameter slightly smaller than that of the main body, disposed on the body and aligned with the three orthogonal x, y and z axes through the body of the mandrel, for aligning and shaping the distal portion of the vasoocclusive device as it is wound on the mandrel. Preferably one of the posts **76** is longer than the other posts, to serve as a mandrel for helically winding the proximal portion of the vasoocclusive coil. As is shown in FIG. **14**, in a presently preferred variant of the embodiment of FIGS. **13**A and **13**B, the mandrel **70'** has a main body **72'** that is substantially cubical, with the six cylindrical posts **74'** disposed on each of the faces of the main body, and one of the posts **76'** being longer than the others.

In another presently preferred embodiment illustrated in FIGS. **15**A to **15**F, one or more of the flexible strands forming the vasoocclusive coil are wound around the surface of a mandrel **80** having a substantially spherical main body **82**, with a plurality of circumferential grooves **84** defined on the surface of the main body, and a plurality of posts **86** mounted on the main body of the mandrel for aligning the occlusive device as it is wound on the mandrel.

In another presently preferred embodiment illustrated in FIGS. **16**A to **16**E, one or more of the flexible strands forming the vasoocclusive coil are wound around the surface of a substantially spherical mandrel **90** having a plurality of circumferential grooves **92** for aligning the occlusive device as it is wound on the mandrel.

FIGS. **17**A to **17**E illustrate another presently preferred embodiment of a substantially spherical mandrel **100** having a plurality of circumferential grooves **102** for aligning the occlusive device, in which one or more of the flexible strands forming the vasoocclusive coil are wound around the surface of the mandrel.

The surface of the mandrel may also have one or more apertures for receiving one or more ends of the strands, to assist winding into the desired form. The wound occlusive device is preferably heat treated at a suitable temperature and a sufficient period of time to impart the form to the shape memory material included in the device. While heat treatment at a temperature of about 1100° F. for approximately 4 hours or more is typically sufficient to impart the form to the occlusive device when the shape memory material is a nickel titanium super-elastic alloy, although the temperature utilized can be substantially lowered, and the duration of heat treatment adjusted accordingly, as will be appreciated by those skilled in the art. After the heat treatment, the occlusive device is removed from the mandrel, and cold worked into the desired collapsed elongated configuration for placement into a catheter or cannula for use. When the occlusive device reaches its destination in the vasculature during vascular therapy, it assumes the primary shape imparted from the heat treatment on the mandrel.

It will be apparent from the foregoing that while particular forms of the invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

What is claimed is:

1. A vasoocclusive device that is adapted to be inserted into a portion of a vasculature for occluding the portion of the vasculature for use in interventional therapy and vascular surgery, comprising:

at least one multi-stranded micro-cable formed to have a first inoperable, substantially linear configuration for insertion into and through a catheter to a desired portion of the vasculature to be treated, and a second operable, three dimensional configuration for occluding the desired part of the vasculature to be treated; said vasoocclusive device further having a distal portion having a second operable, three dimensional shape for filling the anatomical cavity at the site in the vasculature to be treated, and a proximal portion having a second operable, substantially linear shape for filling and reinforcing the distal, three dimensional shaped portion when the vasoocclusive device is implanted at the site in the vasculature to be treated, each said multi-stranded micro-cable having a plurality of flexible strands of a resilient material comprising a central core, and at least one radiopaque strand to provide a radiopaque marker of the deployed configuration of a device made of the cable during vascular surgery.

2. The vasoocclusive device of claim **1**, wherein said distal portion has a second operable, three dimensional shape that is substantially spherical.

3. The vasoocclusive device of claim **1**, wherein said proximal portion is substantially linear.

4. The vasoocclusive device of claim **1**, wherein said proximal portion is substantially helical.

5. The vasoocclusive device of claim **1**, wherein said plurality of strands are helically wound.

6. The vasoocclusive device of claim **1**, wherein said plurality of flexible strands are parallel longitudinal strands.

7. The vasoocclusive device of claim **1**, wherein at least one of said plurality of strands comprises a super-elastic material.

8. The vasoocclusive device of claim **1**, wherein said plurality of flexible strands of a resilient material are comprised of a shape memory material.

9. The vasoocclusive device of claim **8**, wherein said shape memory material comprises a nickel-titanium alloy.

10. The vasoocclusive device of claim **9**, wherein said shape memory nickel-titanium alloy is heat treated such that the alloy is highly flexible at a temperature appropriate for introduction into the body via a catheter, and after placement, the device will take on the primary coil configuration.

11. The vasoocclusive device of claim **8**, wherein said shape memory material comprises a shape memory polymer.

12. The vasoocclusive device of claim 1, wherein said plurality of strands comprises a plurality of exterior strands surrounding at least one interior strand.

13. The vasoocclusive device of claim 1, wherein said plurality of strands comprises a plurality of exterior strands surrounding said central core.

14. The vasoocclusive device of claim 1, wherein said radiopaque strand comprises at least one centrally, axially disposed radiopaque wire.

15. The vasoocclusive device of claim 1, wherein said radiopaque wire is made of platinum.

16. The vasoocclusive device of claim 1, wherein said radiopaque wire is made of tungsten.

17. The vasoocclusive device of claim 1, wherein said radiopaque wire is made of gold.

18. The vasoocclusive device of claim 1, wherein said plurality of strands comprises a plurality of radiopaque strands.

19. The vasoocclusive device of claim 1, wherein said central core comprises copper.

20. The vasoocclusive device of claim 1, wherein said central core comprises a copper alloy.

21. The vasoocclusive device of claim 1, wherein said strands of the micro-cable are bundled by at least one outer cover to produce a composite banded cable.

22. A vasoocclusive device that is adapted to be inserted into a portion of a vasculature for occluding the portion of the vasculature for use in interventional therapy and vascular surgery, comprising:

at least one multi-stranded micro-cable formed to have a first inoperable, substantially linear configuration for insertion into and through a catheter to a desired portion of the vasculature to be treated, and a second operable, three dimensional configuration for occluding the desired part of the vasculature to be treated; said vasoocclusive device further having a distal portion having a second operable, three dimensional shape for filling the anatomical cavity at the site in the vasculature to be treated, and a proximal portion having a second operable, substantially linear shape for filling and reinforcing the distal, three dimensional shaped portion when the vasoocclusive device is implanted at the site in the vasculature to be treated, each said multi-stranded micro-cable having a plurality of flexible strands of a resilient material comprising a central core, and at least one radiopaque strand to provide a radiopaque marker of the deployed configuration of a device made of the cable during vascular surgery, and wherein said strands of the micro-cable are bundled by a least one outer cover comprising a sheath to constrain said strands about a longitudinal axis to produce a composite banded cable.

23. The vasoocclusive device of claim 22, wherein said outer cover comprises an outer sheath of material to provide bending stiffness and constrain said strands about said longitudinal axis.

24. The vasoocclusive device of claim 23, wherein said sheath comprises a containment strand wound about said longitudinal strands.

25. The vasoocclusive device of claim 23, wherein said sheath is made of low friction material.

26. The vasoocclusive device of claim 23, wherein said sheath is made of a fluoropolymer.

27. The vasoocclusive device of claim 23, wherein said sheath comprises a heat shrinkable plastic tube.

28. The vasoocclusive device of claim 21, wherein said strands are bundled by a plurality of bands disposed at intervals to produce a composite banded cable.

29. The vasoocclusive device of claim 28, wherein said strands are laid parallel within the composite banded cable.

30. The vasoocclusive device of claim 28, wherein said strands are twisted within the composite banded cable.

31. The vasoocclusive device of claim 28, wherein composite cable comprises a single inner micro-cable.

32. The vasoocclusive device of claim 28, wherein said exterior wrapped cover is wound at varying intervals along the outside to provide variations in the torqueability and stiffness of the composite cable.

33. The vasoocclusive device of claim 32, wherein the width of the outer cover is varied along the composite cable.

34. The vasoocclusive device of claim 28, wherein said outer covering varies in cross section along its length to provide bending stiffness of said composite cable which varies along said composite cable.

35. The vasoocclusive device of claim 21, wherein the number of strands and the degree to which they extend along said composite cable within the outer covering varies along said composite cable.

36. The vasoocclusive device of claim 23, wherein outer covering comprises a plurality of layers formed of different materials in order to provide a graduated bending and stiffness characteristic.

37. The vasoocclusive device of claim 28, wherein said composite microcable comprises a plurality of micro-cables disposed within said outer cover in order to provide desired bending and strength characteristics.

38. The vasoocclusive device of claim 35, wherein said plurality of micro-cables are helically wound within said outer cover.

39. The vasoocclusive device of claim 35, wherein said plurality of micro-cables extend parallel and longitudinally within said outer cover.

40. The vasoocclusive device of claim 35, wherein said plurality of micro-cables are bundled by at least one outer cover to produce said composite banded cable.

41. The vasoocclusive device of claim 40, wherein said plurality of micro-cables are banded at intervals by a plurality of bands.

42. A method of making a vasoocclusive device that is adapted to be inserted into a portion of a vasculature for occluding the portion of the vasculature for use in interventional therapy and vascular surgery, said vasoocclusive device being formed from at least one strand of a flexible shape memory material formed to have a first inoperable, substantially linear configuration for insertion into and through a catheter to a desired portion of the vasculature to be treated, and a second operable, three dimensional configuration for occluding the desired portion of the vasculature to be treated, said vasoocclusive device having a distal portion having a second operable, three dimensionally shape, and a proximal portion having a second operable, substantially linear shape, the method comprising the steps of:

winding at least one strand of a flexible shape memory material about a mandrel in a three dimensional configuration of the vasoocclusive coil to form a distal portion of the vasoocclusive coil;

heating said at least one strand of a flexible shape memory material wound about the mandrel for a sufficient period of time to impart the form to the shape memory material included in the device to form an operable, three dimensional configuration of the vasoocclusive coil;

removing the vasoocclusive coil from the mandrel; and

cold working the vasoocclusive coil into a desired elongated configuration for placement into a catheter or cannula for use.

43. The method of claim 42, wherein the mandrel about which said at least one flexible strand forming the vasoocclusive coil is wound has a substantially spherical body portion having a plurality of circumferential grooves to form a three dimensional configuration of a distal portion of the vasoocclusive coil.

44. The method of claim 42, wherein the mandrel about which said at least one flexible strand forming the vasoocclusive coil is wound has a main body with a plurality of posts disposed on the body.

45. The method of claim 44, wherein six posts are disposed on the body aligned with the three orthogonal x, y and z axes through the body of the mandrel, for aligning and shaping the distal portion of the vasoocclusive device as it is wound on the mandrel.

46. The method of claim 44, wherein one of the posts is longer than the other posts, to serve as a mandrel for helically winding the proximal portion of the vasoocclusive coil.

47. The method of claim 44, wherein said main body is substantially spherical.

48. The method of claim 44, wherein said main body is substantially cubical.

49. The method of claim 42, wherein the step of heating comprises heating said at least one strand of a flexible shape memory material wound about a mandrel made of refractory material at a temperature of about 1100° F. for about at least 4 hours.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CO CTION

PATENT NO. : 6,171,326 B1
DATED : January 9, 2001
INVENTOR(S) : David A. Ferrera et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 12, claim 38,
Line 27, change "**35**", to read -- **37** --.

Column 12, claim 39,
Line 30, change "**35**", to read -- **37** --.

Column 12, claim 40,
Line 33, change "**35**", to read -- **37** --.

Signed and Sealed this

Thirteenth Day of November, 2001

Attest:

Nicholas P. Godici

Attesting Officer

NICHOLAS P. GODICI
Acting Director of the United States Patent and Trademark Office